



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

April 25, 2024

Samuel Seifert
samuel.seifert@LPNT.net

No Review

Record #: 4431
Date of Request: April 8, 2024
Facility Name: Maria Parham Health
FID #: 943326
Business Name: DLP Maria Parham Medical Center, LLC.
Business #: 1178
Project Description: Acquisition of a da Vinci Dual Xi Surgical System
County: Vance

Dear Mr. Seifert:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request**, the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Cynthia Bradford
Project Analyst

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR
NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

April 8, 2024

Ms. Micheala Mitchell, Chief
Cynthia Bradford, Project Analyst
NC Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section 2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Maria Parham Health Request for No Review Determination Regarding Acquisition of a Da Vinci Surgical System, Vance County

Dear Ms. Mitchell and Ms. Bradford,

Maria Parham Health (“MPH”) is writing to notify the N.C. Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (“the CON Section” or “the Agency”) of MPH’s plans to acquire a da Vinci Surgical System to be located in an operating room (“OR”) on MPH’s main hospital surgical suite in Henderson, Vance County, North Carolina. MPH’s license number is H0267-A. Details regarding the equipment being acquired and its cost are set forth below.

The purpose of this letter is to request that the Agency issue a “No Review Determination” and thereby confirm in writing that MPH’s acquisition of the da Vinci system, on the terms described herein, is not subject to CON Section review and does not require that MPH obtain a certificate of need (“CON”) before acquiring the da Vinci System.

Project Description

MPH plans to acquire a da Vinci Dual Xi Surgical System. This will be MPH’s first da Vinci surgical robotics system. The cost of the da Vinci Xi System will be \$1,770,000.00. The da Vinci Xi will be acquired through a capital lease which, for CON purposes, is the equivalent of an equipment purchase. The acquisition will include a 100NX Sterrad and an Ultrasonic Cleaner for sterilization, which together will add \$166,260 to the capital cost.

The equipment is movable and requires no modifications to the building. Hence, no construction costs are involved.

MPH’s total capital expenditure will total \$1,936,260. See [Attachment 1](#) for a summary of the projected capital cost and [Attachment 2](#) for vendor quotes from Intuitive, ASP, and Getinge.

Applicable Legal Authorities

The CON Law precludes any person from offering or developing a “new institutional health service” without first obtaining a CON. N.C. Gen. Stat. § 131E-178(a). The definition of “new institutional health service” includes, inter alia, the following:

- Incurring an obligation for a capital expenditure that exceeds \$4,000,000.00 to develop or expand a health service or health service facility, or which “relates” to the provision of a health service. Beginning September 30, 2022, and on September 30 each year thereafter, the cost threshold amount in this subdivision shall be adjusted using the Medical Care Index component of the Consumer Price Index published by the U.S. Department of Labor for the 12-month period preceding the previous September 1.; and
- The acquisition by purchase, donation, lease, transfer or comparable arrangement of “major medical equipment,” which is defined as a single unit or single system of components used to provide medical and health services which costs more than \$2,000,000.00/ In determining whether the major medical equipment costs more than two million dollars (\$2,000,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment. Beginning September 30, 2022, and on September 30 each year thereafter, the cost threshold amount in this subdivision shall be adjusted using the Medical Care Index component of the Consumer Price Index published by the U.S. Department of Labor for the 12-month period preceding the previous September 1.{N.C. Gen. Stat. §§ 131E-176(16)(b), (16)(p) and (14o).

The referenced adjustment required by SL 2023-7, reduced the threshold amount to \$1,980,800 for FY 2024, per letter from Micheala Mitchell, on October 30,2023.

Conversely, the acquisition of medical equipment that does not cost more than \$1,980,800.00 does not qualify as “major medical equipment;” does not constitute a “new institutional health service;” and is not subject to “Agency review or the requirement to obtain a CON.”

Because MPH’s new da Vinci Xi System costs less than \$1,980,800 dollars, it does not constitute major medical equipment under the CON Statute. Therefore, no further review of the proposed acquisition by the CON Section is required and MPH is not required to obtain a CON for equipment identified as a “new institutional health service” by N.C. Gen. Stat. § 131E-176(16)f which, if listed in that statutory section, require a CON regardless of cost.¹

MPH’s proposed new da Vinci Xi System does not qualify as a new institutional health service under any other provision of the CON Statute either.

The Agency Has Issued Previous No Review Letters for DaVinci Acquisitions

The Agency has recently approved the acquisition of da Vinci Surgical Systems for other health care providers in response to No Review or Exemption Requests. Recent examples of those include:

¹ MPH acknowledges that medical equipment which costs less than \$1,980,800 may also qualify as a new institutional health service under other provisions of the CON Statute, such as N.C. Gen. Stat. § 131E-176 (7a) (governing diagnostic centers). The da Vinci Surgical System being acquired by MPH does not fall within the ambit of that statutory provision or any other provision of the CON Statute defining “new institutional health services.”

1. January 6, 2020 approval of an No Review Request to acquire a da Vinci Surgical System by New Hanover Regional Medical Center (Record #3174);
2. March 16, 2020 approval of a No Review Request to acquire a da Vinci Surgical System by Rex Hospital, Inc (Record #3242);
3. August 31, 2021 approval of an No Review Request to acquire a da Vinci Surgical System by New Hanover Regional Medical Center (Record #3670);
4. July 25, 2022, approval of No Review Request to acquire a da Vinci Surgical System by MH Mission Hospital, LLLP (Record #3990); and,
5. January 5, 2023 approval of No Review Request to acquire a da Vinci Surgical System by MH Mission Hospital, LLLP (Record #4104).

See [Attachment 3](#) for excerpted copies of these approved No Review Requests.

Conclusion

Based on the information provided in this No Review Determination Request, and in keeping with the Agency's recent practice regarding the determination that da Vinci Surgical Systems which cost less than \$1,980,800 are not subject to CON Section Review and do not require a CON, MPH respectfully requests that the Agency confirm in writing at its earliest opportunity that MPH's acquisition of an additional da Vinci Surgical System is not subject to further CON Section review and does not require a CON.

Please let us know if you have any questions regarding this request.

Sincerely,



Bert Beard
Chief Executive Officer
Maria Parham Health
A Duke Lifepoint Hospital

ATTACHMENT 1

Projected Capital Cost Form – DLP Maria Parham Hospital da Vinci Robot

Building Purchase Price	\$0.00
Purchase Price of Land	\$0.00
Closing Costs	\$0.00
Site Preparation	\$0.00
Construction/Renovation Contract(s)	\$0.00
Landscaping	\$0.00
Architect / Engineering Fees	\$0.00
Medical Equipment	\$1,925,748
Non-Medical Equipment	\$0
Furniture	\$0.00
Consultant Fees (specify)	\$0.00
Financing Costs	\$0.00
Interest during Construction	\$0.00
Other (Sales Tax)	\$10,513*
Other (Transportation)	Included in eq cost
Total Capital Cost	\$1,936,260

*DaVinci cost includes tax

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

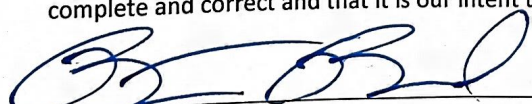
I certify that, to the best of my knowledge, the projected capital cost for the proposed project is complete and correct.

Not applicable
Signature of Licensed Architect or Engineer

Date Signed: _____

CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT

I certify that, to the best of my knowledge, the projected total capital cost for the proposed project is complete and correct and that it is our intent to carry out the proposed project as described.


Signature of Officer/Agent
Bert Beard, CEO DLP Maria Parham Hospital

Date Signed: 4-12-24



Intuitive Surgical, Inc.
1020 Kifer Road
Sunnyvale, CA 94086
800-876-1310

Quote Details

Company Information

Quote ID	Q-00043860
Quote Date	2/22/2024
Valid Until	03/31/2024
Sales Rep	Shelby Smith
Phone Number	+1-832-314-6924
Email	shelby.smith@intusurg.com

Hospital Name	Maria Parham Hospital
SF ID/IDN Affiliation	13707/LifePoint Health
Address	566 Ruin Creek Rd
City, State, Zip	Henderson, North Carolina, 27536-2957
Contact Name	
Telephone	

Please submit orders electronically via GHX or fax to 408-523-2377

Part Number	Qty	Item	Price	Discount	Subtotal
Systems					
	1	da Vinci Xi® Single Console System One (1): da Vinci Xi System Surgeon Console One (1): da Vinci Xi System Patient Cart One (1): da Vinci Xi System Vision Cart da Vinci Xi System Documentation da Vinci Xi System Software Training Instrument Starter Kit Accessory Starter Kit Drapes Vision Equipment (All Kits subject to change without notice)	\$ 1,900,000.00	\$ 200,000.00	\$ 1,700,000.00
Upgrades					
	1	E-100 Generator	\$ 25,000.00	\$ 5,000.00	\$ 20,000.00
	1	Da Vinci Xi Table Motion Upgrade	\$ 75,000.00	\$ 25,000.00	\$ 50,000.00
Freight					
	1	System Freight - East (AL, CT, DC, DE, FL, GA, IN, KY, MA, MD, ME, MI, MS, NC, NH, NJ, NY, OH, PA, RI, TN, SC, VA, VT, WV)	\$ 13,000.00	\$ 13,000.00	\$ 0.00
Total					\$ 1,770,000.00

Part Number	Months	Item	Price	Discount	Annual Service Fee
Service					
	12	da Vinci Xi-Single Console-Human Use (Systems)-SERVICE PLAN : DVCOMPLETE CARE-Warranty (Included)	\$ 0.00	\$ 0.00	\$ 0.00
	48	da Vinci Xi-Single Console-Human Use (Systems)-SERVICE PLAN : DVCOMPLETE CARE-After Warranty Service (Annual)	\$ 154,000.00	\$ 20,000.00	\$ 134,000.00

Terms and Conditions

1) System Terms and Conditions:

1.1 A signed Sales, License, and Service Agreement ("SLSA") or equivalent is required prior to shipment of the System(s). All site modifications and preparation are the Customer's responsibility and are to be completed to the specification given by Intuitive Surgical prior

to the installation date. Delivery is subject to credit approval. Payment terms are Net 30 days from Intuitive Surgical's invoice date. Each System includes the patient side cart, vision cart, and surgeon console(s). System enhancements required to support new features may be purchased at Intuitive Surgical's then current list price. The price of the da Vinci® Surgical System includes the initial installation of the System at Customer's facility and a one (1) year warranty for manufacture defect. All taxes and shipping charges are the responsibility of the Customer and will be added to the invoice, as appropriate.

1.2 Intuitive makes no representation with regard to Certificate of Need requirements for this purchase. It is your (the Customer's) responsibility to determine whether this purchase complies with your State's Certificate of Need laws and what Certificate of Need filing, if any, needs to be made with regard to this purchase.

1.3 Customer acknowledges that the cleaning and sterilization equipment, not provided by Intuitive, is required to appropriately reprocess da Vinci instruments and endoscopes. Please refer to the Intuitive Surgical Reprocessing website: <https://reprocessing.intuitivesurgical.com>. Customer is responsible for ensuring that its' cleaning and sterilization program comply with all health and safety requirements.

2) System Upgrade Terms and Conditions:

2.1 A signed Purchase Order and/or an addendum to the existing Sales, License, and Service Agreement ("SLSA") is required prior to shipment of the System upgrade. All site modifications and preparation are the Customer's responsibility and are to be completed with the specification given by Intuitive Surgical prior to the installation date.

2.2 Payment terms are Net 30 days from Intuitive Surgical's invoice date. The price includes: the System upgrade, the initial installation at Customer's facility and a one (1) year warranty for manufacture defect. All taxes and shipping charges are the responsibility of the Customer and will be added to the invoice, as appropriate. Delivery is subject to credit approval and inventory availability. Standard shipping terms are FCA from Intuitive Surgical™ warehouse. A \$9.95 handling charge will be applied for any shipments using a customer designated carrier.

3) I&A Terms and Conditions:

3.1 To place an order, please fax Purchase Order to Intuitive Surgical Customer Service at 408-523-2377 or submit through the Global Health Exchange (GHX). Payment Terms Net 30 days from invoice date. Delivery is subject to credit approval by Intuitive Surgical. Estimated 2-Day standard delivery. Standard shipping terms are FCA from Intuitive Surgical™ warehouse and are subject to inventory availability. All taxes and shipping charges are the responsibility of the Customer and will be added to the invoice, as appropriate. Pricing is subject to change without notice. A \$9.95 handling charge will be applied for any shipments using a customer designated carrier.

4) Return Goods Policy :

4.1 All returns must be authorized through Intuitive Surgical Customer Service, please call 800-876-1310 to obtain a Return Material Authorization Number (RMA#). All items must be accompanied with valid RMA# for processing and are requested to be received within 14 days of issuance or the RMA could be subject to cancellation. Intuitive Surgical will prepay for the return of the defective instruments. Upon identification of a defective instrument, please call Intuitive Surgical Customer Service within 5 business days. Prior to returning to Intuitive Surgical, items must be cleaned and decontaminated in accordance with the then current local environmental and safety laws and standards. For all excess inventory returns, items are required to be in the original packaging with no markings, seals intact, and to have been purchased within the last 12 months. Package excess returned inventory in a separate shipping container to prevent damage to original product packaging.

5) Exchange Goods Policy :

5.1 Repairs to Endoscope, Camera Head and Skills Simulators may qualify for Intuitive Surgical advanced exchange program. Please contact Customer Service or send email to CustomerSupport-ServiceSupport@intusurg.com to obtain information on our current exchange program.

6) Credit Policy :

6.1 Intuitive Surgical will issue credit against original purchase order after full inspection is complete. Credit for defective returns: Intuitive Surgical will issue credit on products based on failure analysis performed and individual warranty terms. For instruments, credit will be issued for the remaining lives, plus one additional life to compensate for usage at the time the issue was identified. Evidence of negligence, misuse and mishandling will not qualify for credit. Credit for excess inventory returns: Excess Inventory returns will be valued at the invoice price. Original packaging must be unmarked, undamaged and seals intact to qualify for credit. Credit will be issued if the products were shipped less than 12 months prior to return request, the original package is intact and the product is within expiration date. Intuitive Surgical will retain all returned product.

7) Miscellaneous :

7.1 Warranty: Warranties are applied for manufacturing defects. Endoscope, Camera, Simulator, and System upgrades – 1 year warranty. Accessories – 90 day warranty. Instruments: see above for credit.

7.2 Any term or condition contained in your purchase order or similar forms which is different from, inconsistent with, or in addition to these

terms shall be void and of no effect unless agreed to in writing and signed by your authorized representative and authorized representative of Intuitive Surgical. The terms and conditions of this quote, including pricing, are confidential and proprietary information of Intuitive Surgical and shall not be disclosed to any third party without the consent of Intuitive Surgical.

For questions please contact Customer Service at 800-876-1310

EXHIBIT A
Deliverables, Price and Delivery

da Vinci® Xi™ Single Console System (Firefly™ Fluorescence Imaging Enabled)

One (1): da Vinci® Xi™ System Surgeon Console
One (1): da Vinci® Xi™ System Patient Cart
One (1) da Vinci® Xi™ System Vision Cart
Warranty period: One (1) year from the Acceptance.

da Vinci® Xi™ System Documentation including:

User's Manual For System
Warranty period: n/a

User's Manual for Instruments and Accessories
Warranty period: n/a

One (1) da Vinci® Xi™ Cleaning & Sterilization Kit
Warranty period: 90 days from Acceptance
Two (2) da Vinci® Xi™ Instrument Release Kit (IRK)
Warranty period: 90 days from Acceptance

da Vinci® Xi™ System Software

Warranty period: One (1) year from the Acceptance.

Instrument and Accessories including:

Accessory Starter Kit

Two (2): Box of 6: 8 mm Bladeless Obturator
One (1): 8 mm Blunt Obturator
Four (4): Box of 10: 5 mm - 8 mm Universal Seal
Four (4): 8 mm Cannula
Three (3): Monopolar Energy Instrument Cord
Three (3): Bipolar Energy Instrument Cord
One (1): Box of 3: da Vinci® Xi™ Gage Pin
Three (3): Instrument Introducer
One (1): Box of 10: Tip Cover for Hot Shears™ (MCS)
One (1): Pmed Cable, Covidien ForceTraid ESU
Warranty period: 90 days from Acceptance

Drapes

Two (2): Pack of 20 da Vinci® Xi™ Arm Drape
One (1): Pack of 20 da Vinci® Xi™ Column Drape
Warranty period: 90 days from Acceptance

Vision Equipment:

Two (2): da Vinci® Xi™ Endoscope with Camera, 8 mm 0 degree
Two (2): da Vinci® Xi™ Endoscope with Camera, 8 mm 30 degree
Four (4): da Vinci® Xi™ Endoscope Sterilization Trays
Warranty period: One (1) year from the Acceptance.

Training Instrument Starter Kit

One (1): Large Needle Driver
One (1): ProGrasp™ Forceps
One (1): Maryland Bipolar Forceps
One (1): Hot Shears™ (Monopolar Curved Scissors)
One (1): Tip-Up Fenestrated Grasper
One (1): Mega™ SutureCut™ Needle Driver
Warranty period: 90 days from Acceptance

(all kits subject to change without notice) (rev 4/2015)

Sales Quotation For: MARIA PARHAM MEDICAL CENTER



Account Manager:

Brian Argotti

ASP

704-883-6048

brian.argotti@asp.com

ASP has a long track record designing and delivering innovative infection prevention solutions that dramatically raise the level of healthcare and safety for those who matter most. Our pioneering technology, global distribution, and established leadership position enable us to simplify the process of buying and operating infection prevention products and services every day, for thousands of medical facilities around the world.

Sold-to

Account Number 8024758
 MARIA PARHAM MEDCL CTR
 566 RUIN CREEK RD
 HENDERSON NC 27536-2927

Quotation

Quote Number	1300509103
Valid from	Mar 8, 2024
Valid to	Jun 6, 2024

Ship-to

Account Number 8024758
 MARIA PARHAM MEDCL CTR
 566 RUIN CREEK RD
 HENDERSON NC 27536-2927

Make orders out to:

ADVANCED STERILIZATION PRODUCTS SERVICES, INC.
 33 TECHNOLOGY DR
 IRVINE CA 92618

Conditions:

Promotional discounts are subject to all terms and conditions of that promotion, including purchase order delivery and shipping dates. Please see our promotional offer enclosed. Delivery contingent on inventory position. Pricing is subject to change without notice after the validity date above.

Group Purchasing Organization pricing below has been provided based upon the Customer's representation that it is a member in good standing of that Group Purchasing Organization and eligible to participate under the Group Purchasing Organization's agreement. Any failure by Customer to meet membership requirements, may result in a price adjustment. This information is confidential and may not be shared with any third party without the prior written consent of ASP. Sales under a contract agreement will be subject to all terms and conditions of that agreement. Pricing and terms per contract. Otherwise, list price and standard terms of sale apply: https://www.asp.com/sites/default/files/pdf/ASP_NA_ToS_US.pdf.

Item	Qty	Product	Item Detail	Unit Price	Value
10	1	10104-007-50	ST100NX ALLCLEAR 1-DR DUO		
		ASP List Price		245,000.00	245,000.00
		HPG HPG-500155 LTS Cont Price		145,000.00	145,000.00
		Discount 1		-26,260.00	-26,260.00
		Net Value		118,740.00	118,740.00

Quote Total without Tax in USD

118,740.00

This is not a bill. Do not submit payment based on this document. Fees, freight and taxes will be applied when ordered & invoiced.

For inquiries, please contact Customer Services at 888-783-7723.

THIS DOCUMENT CONTAINS CONFIDENTIAL AND PROPRIETARY TRADE SECRETS OF ADVANCED STERILIZATION PRODUCTS SERVICES INC. ITS CONTENTS MAY NOT BE DISCLOSED BY AN AUTHORIZED RECIPIENT WITHOUT THE PRIOR WRITTEN CONSENT OF ADVANCED STERILIZATION PRODUCTS SERVICES INC.



Trade-In

1. Customers will be eligible for applicable discounts and pricing only by allowing ASP to take possession of existing equipment or by certifying disposal of such equipment. Please note that the price is contingent on the receipt of fully executed Agreement. All discounts, if any, provided under this Agreement are intended to comply with the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). To the extent required by 42 C.F.R. § 1001.952(h) (the Anti-Kickback Statute discount safe harbor regulations) or other applicable laws and regulations, Customer must fully and accurately disclose any discount/rebate provided under this Agreement, as required, in any submissions to federal healthcare programs and, upon request by the Secretary of the U.S. Department of Health and Human Services or a state agency, must make available information provided to buyer by seller concerning the discounts.
 - a) The Customer must return each Unit to the Company no later than 60 days following the installation and validation of the new ASP Equipment replacing that Unit. Following installation and validation of the new ASP Equipment, the Customer will not use the replaced Unit(s). The Customer hereby sells, transfers and assigns to the Company, and the Company hereby accepts the sale, transfer and assignment of the Customer's right, title and interest in each Unit as of the date that the possession of the Unit is transferred to the Company. If the Unit is not returned within the required time frame, the Customer will be invoiced for the amount of the credit received as part of this agreement for that Unit.
 - b) The Customer must disconnect and decontaminate each Unit for pick-up by the Company. A Unit may not be returned unless the Company has assigned a Return Goods Authorization number to the Unit. The Company will pack, load and remove the Unit(s); provided that the Customer must arrange and cooperate with the Company, at no additional cost, in the removal of the Unit(s) from the Customer's premises. The removal of the Unit(s) without separate charge may constitute a discount that, to the extent required by applicable law, the Customer will allocate and disclose. Coordination of the removal of the aged equipment will take place with the ASP de-installation team upon the installation of the replacement ASP system.
 - c) The Customer represents and warrants that it has good and marketable title to the Unit(s), free and clear of all liens, security interests and other encumbrances and that the Unit(s) will remain free and clear of all encumbrances until title and possession is transferred to the Company.



Installation Options

Dear Customer,

Thank you for purchasing our STERRAD® Sterilization System(s). The purpose of this letter is to make you aware of the installation options that are available to you. You may choose one of the following options:

- **Advanced Sterilization Products (ASP):** Installation by ASP can be purchased. ASP will coordinate with the Customer and perform installation, and validation of the unit. The one-year service warranty will begin immediately following validation of the unit for Customer use. Validation of the unit should be performed as soon as possible (often performed same day as the installation), or no later than three months, when the unit is unpackaged due to required on-site inspections, however no later than twenty-four months.

-or-

- **Universal Hospital Services (UHS):** You may choose to independently coordinate installation/validation through a third-party vendor. Pricing will be provided by the vendor. To be put in touch with a trained third-party vendor, please contact our Customer Service Department at 888-783-7723.

-or-

- **“Self” Install Equipment:** You may choose to install the equipment yourself. You will be required to purchase the necessary tools to install the equipment. Failure to follow the directions in the Installation Guide may void the equipment warranty.

If you have any questions or would like to schedule installation of your STERRAD® Sterilization System, please reach out to your ASP Corporate Account Director, ASP Account Manager, or our Customer Service Department at 888-783-7723.

Again, thank you for choosing ASP for your low-temperature sterilization needs. We value your partnership and appreciate your business.

Sincerely,

ASP Global Marketing



GETINGE 

Your Expert Partner in Sterile Processing

Equipment | Consulting | Workflow | Consumables

Orinthia Thompson

MARIA PARHAM MEDICAL CENTER / 134551

566 RUIN CREEK ROAD

HENDERSON, North Carolina 27536

Quote Date: 12/20/2023

Follow Us!





Getinge USA Sales, LLC
1 Geoffrey Way, Wayne NJ 07470
Bethany Grant,
bethany.grant@getinge.com

MARIA PARHAM MEDICAL CENTER / 134551
566 RUIN CREEK ROAD, HENDERSON, North Carolina 27536
Orinthia Thompson, SPD Manager
(252) 438-4143

Quote Number: 000323823.3
12/20/2023

Getinge USA Sales, LLC (“Getinge”) is pleased to submit the following quotation for the products and services described herein at the stated prices and terms, subject to your acceptance of the terms and conditions as listed below and/or on all attached pages. This quotation is subject to final approval by Getinge and is not considered firm or binding until accepted by the corporate offices and an order acknowledgement is issued to you (“Customer”). This proposal and pricing terms are considered proprietary and confidential. This document cannot be shared or provided to any other 3rd party organization or personnel without the expressed written consent of Getinge.

This quotation is in US dollars:

Valid until 3/19/2024

Proposal based on: HPG IC EQ T1 HPG-81849

Shipping terms: FOB Origin – Freight Prepaid and Added

Freight charges and applicable taxes, if any, are payable upon receipt of invoice. Freight charges equal to 10% of the quote value applied to all Detergent and Consumables orders. Delivery subject to availability

Connecting the Infection Control devices in your facility with Getinge Online brings life cycle and preventive maintenance data together for ease of equipment management, service diagnosis, and overall analytics through an easy to read web-based format. Getinge Online, valued at \$495 per unit, is offered on an annual basis. Any discount offered for the first year of the subscription will expire after the conclusion of the year and the subscription price for Getinge Online will return to the list price thereafter. Should the customer choose not to subscribe to Getinge Online, Getinge reserves the right to maintain connectivity to the device for Getinge’s remote diagnostic purposes

UNLESS THIS QUOTATION HAS BEEN DESIGNATED BY GETINGE AS BEING GOVERNED BY AN APPLICABLE GROUP PURCHASING ORGANIZATION OR INTEGRATED DELIVERY NETWORK AGREEMENT, THIS QUOTATION WILL BE GOVERNED BY GETINGE’S STANDARD CONDITIONS OF SALE FOUND AT: getinge.com/salesandserviceterms. Any prior or collateral agreements, representations, promises or conditions, whether written or oral, in connection herewith, are superseded hereby. No modifications, waivers or termination of any provisions contained in this Agreement or any future agreements, representations, promises or conditions in connection with the subject matter hereof shall be binding upon Getinge unless made in writing and signed by an authorized officer thereof. Acceptance of any Customer’s purchase order does not operate as acceptance of any different or additional terms. None of Getinge’s terms may be rejected or revoked by Customer without the consent of Getinge’s Legal Team. If you have any questions about this Agreement, please contact your local Getinge Sales Representative. By signing this Quotation, you agree that you have reviewed and accepted Getinge’s Standard Conditions of Sale available at getinge.com/salesandserviceterms, and that you accept and agree to all of the terms hereof.

PRESENTED BY:

Name: Bethany Grant
Title:
Date: 12/20/2023

CUSTOMER'S ACCEPTANCE

By: _____
Name: Orinthia Thompson
Title: SPD Manager
Date: _____



Getinge USA Sales, LLC
1 Geoffrey Way, Wayne NJ 07470
Bethany Grant,
bethany.grant@getinge.com

MARIA PARHAM MEDICAL CENTER / 134551
566 RUIN CREEK ROAD, HENDERSON, North Carolina 27536
Orinthia Thompson, SPD Manager
(252) 438-4143

Quote Number: 000323823.3
12/20/2023

GETINGE PRODUCT QUOTE SUMMARY

Description	Total Price
1101 Ultrasonic Cleaner for da Vinci	\$ 33,825.53
Installation	\$ 1,200.00
<i>Optional Products for Installation</i>	\$ 1,982.00

GETINGE proposal total (without Optional Products) : \$ 35,025.53

GETINGE proposal total (with Optional Products): \$ 37,007.53

Through Getinge Financial Services, we offer alternatives outside of a cash purchase. Our acquisition solutions can be tailored to meet the specific financial and strategic needs of your organization. If you would like to learn more, please reach out to your sales representative.



Getinge USA Sales, LLC
 1 Geoffrey Way, Wayne NJ 07470
Bethany Grant,
 bethany.grant@getinge.com

MARIA PARHAM MEDICAL CENTER / 134551
 566 RUIN CREEK ROAD, HENDERSON, North Carolina 27536
Orinthia Thompson, SPD Manager
 (252) 438-4143

Quote Number: 000323823.3
 12/20/2023

1101 Ultrasonic Cleaner for da Vinci
Quote Line Items

Part Number	Description	Qty	Unit List Price	Unit Contract Price	Unit Discounted Price	Extended Discounted Price
6003000801	COUNTERTOP ULTRASONIC SYSTEM	1	\$47,948.00	\$26,940.33	\$26,940.33	\$26,940.33
Description: Model 1101-TRT Countertop Ultrasonic Cleaning System for Complex Surgical Instruments						
Tabletop Cart		1	\$4,724.00	\$2,723.38	\$2,723.38	\$2,723.38
6003000826	TABLETOP CART,SST,W/CASTERS	1	\$4,724.00	\$2,723.38	\$2,723.38	\$2,723.38
Description: Stainless Steel Tabletop Cart w/ Casters						
Trays/Baskets		1	\$7,219.00	\$4,161.82	\$4,161.82	\$4,161.82
6003000810	BASKET W/ADAPTER KIT, 1101	1	\$1,397.00	\$805.45	\$805.45	\$805.45
Description: Lumen Basket with Adapter Kit, 1101						
6003000858	1101 Xi TRAY W/Xi ADAPTERS,6	1	\$4,723.00	\$2,722.73	\$2,722.73	\$2,722.73
Description: 1101 Xi TRAY W/Xi ADAPTERS						
6003000828	WIRE MESH BASKET	1	\$276.00	\$159.19	\$159.19	\$159.19
Description: Wire Mesh Basket, 10"W x 21"L x 4"H						
6003000844	ADAPTERS,TRITON XI,10 PACK	1	\$823.00	\$474.45	\$474.45	\$474.45
Description: Triton XI Adapters, 10 Pack						
Total Price:						\$ 33,825.53



Getinge USA Sales, LLC
1 Geoffrey Way, Wayne NJ 07470
Bethany Grant,
bethany.grant@getinge.com

MARIA PARHAM MEDICAL CENTER / 134551
566 RUIN CREEK ROAD, HENDERSON, North Carolina 27536
Orinthia Thompson, SPD Manager
(252) 438-4143

Quote Number: 000323823.3
12/20/2023

Installation
Quote Line Items

Part Number	Description	Qty	Unit List Price	Unit Contract Price	Unit Discounted Price	Extended Discounted Price
ZSUS7749-I-1101	Install TRT Counter Ultrasonic	1	\$1,300.00	\$1,200.00	\$1,200.00	\$1,200.00
Total Price:						\$ 1,200.00



Getinge USA Sales, LLC
1 Geoffrey Way, Wayne NJ 07470
Bethany Grant,
bethany.grant@getinge.com

MARIA PARHAM MEDICAL CENTER / 134551
566 RUIN CREEK ROAD, HENDERSON, North Carolina 27536
Orinthia Thompson, SPD Manager
(252) 438-4143

Quote Number: 000323823.3
12/20/2023

Optional Products for Installation Quote Line Items

Part Number	Description	Qty	Unit List Price	Unit Contract Price	Unit Discounted Price	Extended Discounted Price
ZSUSINSTAL-WKD-XHR	Weekend/Afterhours (per piece)	1	\$2,147.00	\$1,982.00	\$1,982.00	\$1,982.00
Total Price:						\$ 1,982.00



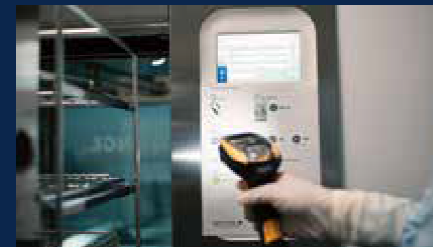
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NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor ATTACHMENT 3
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

January 6, 2020

Kristy Hubard
2131 S. 17th Street
Wilmington, NC 28401

No Review

Record #: 3174
Facility Name: New Hanover Regional Medical Center
FID #: 943372
Business Name: New Hanover Regional Medical Center
Business #: 1308
Project Description: Acquire DaVinci XI Surgical System
County: New Hanover

Dear Ms. Hubard:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in that correspondence is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

You may need to contact the Agency's Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Tanya M. Saporito
Project Analyst

Martha J. Frisone
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873



November 25, 2019

Ms. Martha Frisone, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

RE: Request for Exemption to Certificate of Need Review for Acquisition of an Intuitive daVinci Xi Surgical System / New Hanover County

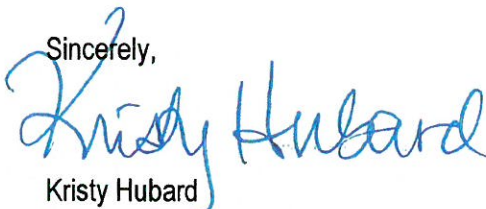
Dear Ms. Frisone,

This letter is intended to provide advance notice to the Healthcare Planning and Certificate of Need ("CON") Section that New Hanover Regional Medical Center ("NHRMC") is planning to acquire medical equipment, specifically, an Intuitive daVinci Xi Surgical System for use at the hospital. The total cost of the medical equipment is \$725,000. There are no other project costs associated with the acquisition of the medical equipment.

Under the CON statute, robotic surgical system equipment is not specifically subject to CON review unless the cost of acquiring the equipment meets the \$750,000 threshold for "Major Medical Equipment" set forth in N.C.G.S. 131E-176(140). Here the cost of the equipment, including all costs to make the equipment operational, will not exceed \$750,000. Accordingly, NHRMC requests that the Section issue a written determination confirming that its proposed acquisition of an Intuitive daVinci Xi Surgical System to be located on its main campus is not subject to CON review.

If you have any questions or need additional information, please do not hesitate to contact me at (910) 667-7000.

Sincerely,



Kristy Hubard
Chief Strategy Officer
New Hanover Regional Medical Center

NHRMC 943372
NR id 3174
BUS 1308



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

March 16, 2020

Elizabeth Runyon, System Director of Regulatory Affairs & Special Counsel
UNC Health Care
Hedrick Building
211 Friday Center Drive, Suite G014
Chapel Hill NC 27517

No Review

Record #: 3242
Facility Name: Rex Hospital
FID #: 953429
Business Name: Rex Hospital, Inc.
Business #: 1554
Project Description: Acquisition of da Vinci Xi Surgical System
County: Wake

Dear Ms. Runyon:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in that correspondence is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

You may need to contact the Agency's Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,
Michael J. McKillip
Project Analyst

Martha J. Frisone
Martha J. Frisone
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
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https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



March 5, 2020

VIA ELECTRONIC MAIL

Mr. Michael J. McKillip
Certificate of Need Section
Division of Health Service Regulation
Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27603
mike.mckillip@dhhs.nc.gov

Re: Request for No Review Determination / Acquisition of da Vinci Xi Surgical System/
Rex Hospital / Wake County

Dear Mr. McKillip:

Rex Hospital, Inc. ("UNC Rex") is planning to purchase a da Vinci Xi Surgical System, which is a robotic system used to assist in minimally invasive laparoscopic surgical procedures. The purchase price of this system is \$725,000 and the delivery charge is \$10,000, resulting in a total cost of \$735,000 which UNC Rex will incur to acquire the equipment and make it operational. *See* Exhibit 1. No renovations or upfit are required in order for the robotic system to be accommodated and operationalized within the hospital, and there are no other costs that UNC Rex must incur to acquire the equipment and make it operational.

UNC Rex is requesting written confirmation that this proposed acquisition of the da Vinci Xi Surgical System does not require CON review, because the acquisition does not meet the definition of "major medical equipment" as contained in N.C. Gen. Stat. § 131E-176(14f), and it does not constitute any other type of "new institutional health service" requiring a CON as that term is defined in N.C. Gen. Stat. § 131E-176(16).

If you require any additional information regarding this project, please do not hesitate to contact me at 984-215-3622 or elizabeth.runyon@unchealth.unc.edu.

Sincerely,

A handwritten signature in cursive script that reads "Elizabeth Runyon".

Elizabeth Runyon
System Director of Regulatory Affairs & Special Counsel
UNC Health Care



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

August 31, 2021

Kristy Hubard
Kristy.hubard@nhrmc.org

No Review

Record #: 3670
Date of Request: August 19, 2021
Facility Name: Novant Health New Hanover Regional Medical Center
FID #: 943372
Business Name: Novant Health New Hanover Regional Medical Center, LLC
Business #: 3330
Project Description: Acquire two Intuitive daVinci Xi Surgical Systems
County: New Hanover

Dear Ms. Hubard:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request**, the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Tanya M. Saporito

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

**NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION**

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<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

August 19, 2021

Ms. Micheala Mitchell, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

RE: Request for Exemption to Certificate of Need Review for Acquisition of an Intuitive daVinci Xi
Surgical System / New Hanover County
FID # 943372

Dear Ms. Mitchell,

This letter is intended to provide advance notice to the Healthcare Planning and Certificate of Need ("CON") Section that Novant Health New Hanover Regional Medical Center ("NHNHRMC") is planning to acquire medical equipment, specifically, two Intuitive daVinci Xi Surgical Systems for use at the hospital. The individual cost of each medical equipment is \$725,000. There are no other project costs associated with the acquisition of the medical equipment.

Under the CON statute, robotic surgical system equipment is not specifically subject to CON review unless the cost of acquiring the equipment meets the \$750,000 threshold for "Major Medical Equipment" set forth in N.C.G.S. 131E-176(14o). Here the cost of the equipment, including all costs to make the equipment operational, will not exceed \$750,000 each. Accordingly, NHNHRMC requests that the Section issue a written determination confirming that its proposed acquisition of two Intuitive daVinci Xi Surgical Systems to be located on its main campus are not subject to CON review.

If you have any questions or need additional information, please do not hesitate to contact me at (910) 667-5908.

Sincerely,



Kristy Hubard
Chief Strategy Officer
Novant Health New Hanover Regional Medical Center



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

July 25, 2022

Ken Burgess
kburgess@bakerdonelson.com

No Review

Record #: 3990
Date of Request: July 7, 2022
Facility Name: Mission Hospital
FID #: 943349
Business Name: MH Mission Hospital, LLLP
Business #: 3045
Project Description: Acquire a daVinci Xi Surgical System
County: Buncombe

Dear Mr. Burgess:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request**, the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Ena Lightbourne
Project Analyst

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

KENNETH LEE BURGESS, SHAREHOLDER
Direct Dial: 919-294-0802
Direct Fax: 919-338-7696
E-Mail Address: kburgess@bakerdonelson.com

July 7, 2022

VIA EMAIL

micheala.mitchell@dhhs.nc.gov
ena.lightbourne@dhhs.nc.gov

Micheala Mitchell, Chief
Ena Lightbourne, Project Analyst
Healthcare Planning & Certificate of Need Section
N.C. Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: MH Mission Hospital, LLP Request for No Review
Determination Regarding Acquisition of DaVinci Surgical System

Dear Micheala and Ena:

I am writing on behalf of our client, MH Mission Hospital, LLLP (“Mission”) to notify the N.C. Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (“the CON Section” or “the Agency”) of Mission’s plans to acquire a da Vinci Surgical System to be located at the Asheville Surgery Center (“ASC”) which is located at 5 Medical Park Drive in Asheville, North Carolina. The ASC is licensed on the license of Mission Hospital, license number H0036. Details regarding the equipment being acquired and its cost are set forth below. The purpose of this letter is to request that the Agency issue a “No Review Determination” and thereby confirm in writing that Mission’s acquisition of the da Vinci system, on the terms described herein, is not subject to CON Section review and does not require that Mission obtain a certificate of need (“CON”) before acquiring the da Vinci System.

Project Description

Mission plans to acquire a da Vinci Dual Xi Surgical System. This will represent Mission's fifth (5th) da Vinci surgical robotics system. The new da Vinci Xi System will be located in Operating Room # 9 of the ASC. The cost of the da Vinci Xi System will be \$1,738,750.00. The da Vinci Xi will be acquired through a capital lease which, for CON purposes is the equivalent of an equipment purchase. Mission will also acquire a Trumpf Bed designed to work with the da Vinci Xi System which will be purchased from Hillrom at a cost of \$84,896.00. Together, Mission's combined capital expenditure totals \$1,823,646.00. **See Attachment 1** (HCA Mission Capital Approval Memo). See also, **Attachment 2** (Statement of Mission Hospital Chief Operating Officer).

Applicable Legal Authorities

The CON Law precludes any person from offering or developing a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178(a). The definition of "new institutional health service" includes, *inter alia*, the following:

- Incurring an obligation for a capital expenditure that exceeds \$2,000,000.00 to develop or expand a health service or health service facility, or which "relates" to the provision of a health service; and
- The acquisition by purchase, donation, lease, transfer or comparable arrangement of "major medical equipment," which is defined as a single unit or single system of components used to provide medical and health services which costs more than \$2,000,000.00, including the costs of the equipment and all studies, drawings, installation and any other activities essential to acquiring and making the equipment operational.¹

N.C. Gen. Stat. §§ 131E-176(16)(b), (16)(p) and (14o). Conversely, the acquisition of medical equipment that does not cost more than \$2,000,000.00 does not qualify as "major medical equipment;" does not constitute a "new institutional health service; and thus is not subject to Agency review or the requirement to obtain a CON.

Because Mission's new da Vinci Xi System costs less than \$2 million dollars, it does not constitute major medical equipment under the CON Statute. Therefore, no further review of the

¹ In calculating construction costs, our clients relied upon prior Agency determinations that the construction costs "essential to acquiring and making operational the replacement equipment" should include only those costs directly related to removing the old equipment, installing the new equipment and making sure that equipment operates properly. In the case of a CT scanner, for example, such cost should include upfit of the CT room related solely to the operation of the CT scanner (e.g., shielding, extra electrical connections), but need not include other construction costs associated with that room. Similarly, the Agency has previously determined that costs associated with the installation of equipment in the control room for the CT scanner should be included only to the extent that those costs would be different from construction related to general office space. *Mission Hospitals, Inc. v. NC DHHS*, ___ N.C.App. ___, 696 S.E.2d 163 (2010).

proposed acquisition by the CON Section is required and Mission is not required to obtain a CON before acquiring the equipment. Further, surgical robotics systems are not a type of equipment identified as a “new institutional health service” by N.C.Gen. Stat. § 131E-176(16)f which, if listed in that statutory section, require a CON regardless of cost.²

Mission’s proposed new da Vinci Xi System does not qualify as a new institutional health service under any other provision of the CON Statute either.

The Agency Has Issued Previous No Review Letters for da Vinci Acquisitions

The Agency has recently approved the acquisition of da Vinci Surgical Systems for other health care providers in response to No Review or Exemption Requests. Recent examples of those include:

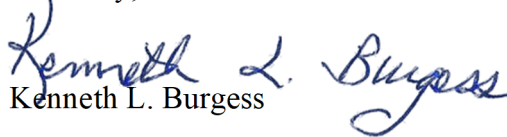
1. January 6, 2020 approval of an Exemption Request to acquire a da Vinci Surgical System by New Hanover Regional Medical Center. **See Attachment 3**
2. March 16, 2020 approval of a No Review Request to acquire a da Vinci Surgical System by Rex Hospital, Inc. **See Attachment 4.**
3. August 31, 2022 approval of an Exemption Request to acquire a da Vinci Surgical System by Novant New Hanover Regional Medical Center. **See Attachment 5.**³

Conclusion

Based on the information provided in this No Review Determination Request, and in keeping with the Agency’s recent practice regarding the determination that da Vinci Surgical Systems which cost less than \$2,000,000.00 are not subject to CON Section Review and do not require a CON, Mission respectfully requests that the Agency confirm in writing at its earliest opportunity that Mission’s acquisition of an additional da Vinci Surgical System is not subject to further CON Section review and does not require a CON.

Please let us know if you have any questions regarding this request.

Sincerely,


Kenneth L. Burgess

² Mission acknowledges that medical equipment which costs less than \$2,000,000.00 may also qualify as a new institutional health service under other provisions of the CON Statute, such as N.C. Gen. Stat. § 131E-176 (7a) (governing diagnostic centers). The da Vinci Surgical System being acquired by Mission does not fall within the ambit of that statutory provision or any other provision of the CON Statute defining “new institutional health services.”

³ Mission does not believe that an Exemption Request is the appropriate vehicle for obtaining confirmation that da Vinci Surgical Systems are not subject to CON Section review because they are not the subject of a statutory exemption from provisions of the CON Statute that would otherwise make them “new institutional health services.” As a result, Mission is requesting a No Review Determination in this case.



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

January 5, 2022

Kenneth Burgess
kburgess@bakerdonelson.com

No Review

Record #: 4104
Date of Request: December 9, 2022
Facility Name: Mission Hospital
FID #: 943349
Business Name: MH Mission Hospital, LLLP
Business #: 3045
Project Description: Acquire daVinci Dual Xi Surgical System
County: Buncombe

Dear Mr. Burgess:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request**, the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Ena Lightbourne, Project Analyst

Micheala Mitchell, Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

KENNETH LEE BURGESS, SHAREHOLDER
Direct Dial: 919-294-0802
Direct Fax: 919-338-7696
E-Mail Address: kburgess@bakerdonelson.com

December 9, 2022

VIA EMAIL

micheala.mitchell@dhhs.nc.gov
ena.lightbourne@dhhs.nc.gov

Micheala Mitchell, Chief
Ena Lightbourne, Project Analyst
Healthcare Planning & Certificate of Need Section
N.C. Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: MH Mission Hospital, LLP Request for No Review
Determination Regarding Acquisition of DaVinci Surgical System

Dear Micheala and Ena:

I am writing on behalf of our client, MH Mission Hospital, LLLP (“Mission”) to notify the N.C. Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (“the CON Section” or “the Agency”) of Mission’s plans to acquire a da Vinci Surgical System to be located in operating room (“OR”) 28 in the main Mission Hospital OR suite in Asheville, North Carolina. Mission Hospital’s license number is H0036. Details regarding the equipment being acquired and its cost are set forth below. The purpose of this letter is to request that the Agency issue a “No Review Determination” and thereby confirm in writing that Mission’s acquisition of the da Vinci system, on the terms described herein, is not subject to CON Section review and does not require that Mission obtain a certificate of need (“CON”) before acquiring the da Vinci System.

P

Project Description

Mission plans to acquire a da Vinci Dual Xi Surgical System. This will represent Mission's sixth (6th) da Vinci surgical robotics system. The cost of the da Vinci Xi System will be \$1,738,750.00. The da Vinci Xi will be acquired through a capital lease which, for CON purposes, is the equivalent of an equipment purchase. The acquisition will include an Integrated Table Motion Upgrade designed to work with the da Vinci Xi System at a cost of \$25,500.00. Together, Mission's combined capital expenditure totals \$1,738,750.00. **See Attachment 1** (Projected Capital Cost Form). See also, **Attachment 2** (Statement of Mission Hospital Chief Operating Officer).

Applicable Legal Authorities

The CON Law precludes any person from offering or developing a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178(a). The definition of "new institutional health service" includes, *inter alia*, the following:

- Incurring an obligation for a capital expenditure that exceeds \$4,000,000.00 to develop or expand a health service or health service facility, or which "relates" to the provision of a health service; and
- The acquisition by purchase, donation, lease, transfer or comparable arrangement of "major medical equipment," which is defined as a single unit or single system of components used to provide medical and health services which costs more than \$2,000,000.00, including the costs of the equipment and all studies, drawings, installation and any other activities essential to acquiring and making the equipment operational.¹

N.C. Gen. Stat. §§ 131E-176(16)(b), (16)(p) and (14o). Conversely, the acquisition of medical equipment that does not cost more than \$2,000,000.00 does not qualify as "major medical equipment;" does not constitute a "new institutional health service; and is not subject to Agency review or the requirement to obtain a CON.

Because Mission's new da Vinci Xi System costs less than \$2 million dollars, it does not constitute major medical equipment under the CON Statute. Therefore, no further review of the proposed acquisition by the CON Section is required and Mission is not required to obtain a

¹ In calculating construction costs, our clients relied upon prior Agency determinations that the construction costs "essential to acquiring and making operational the replacement equipment" should include only those costs directly related to removing the old equipment, installing the new equipment and making sure that equipment operates properly. In the case of a CT scanner, for example, such cost should include upfit of the CT room related solely to the operation of the CT scanner (e.g., shielding, extra electrical connections), but need not include other construction costs associated with that room. Similarly, the Agency has previously determined that costs associated with the installation of equipment in the control room for the CT scanner should be included only to the extent that those costs would be different from construction related to general office space. *Mission Hospitals, Inc. v. NC DHHS*, ___ N.C.App. ___, 696 S.E.2d 163 (2010).

CON before acquiring the equipment. Further, surgical robotics systems are not a type of equipment identified as a “new institutional health service” by N.C. Gen. Stat. § 131E-176(16)f which, if listed in that statutory section, require a CON regardless of cost.²

Mission’s proposed new da Vinci Xi System does not qualify as a new institutional health service under any other provision of the CON Statute either.

The Agency Has Issued Previous No Review Letters for DaVinci Acquisitions

The Agency has recently approved the acquisition of da Vinci Surgical Systems for other health care providers in response to No Review or Exemption Requests. Recent examples of those include:

1. January 6, 2020 approval of an Exemption Request to acquire a da Vinci Surgical System by New Hanover Regional Medical Center. **See Attachment 3**
2. March 16, 2020 approval of a No Review Request to acquire a da Vinci Surgical System by Rex Hospital, Inc. **See Attachment 4.**
3. August 31, 2022 approval of an Exemption Request to acquire a da Vinci Surgical System by Novant New Hanover Regional Medical Center. **See Attachment 5.**³

Conclusion

Based on the information provided in this No Review Determination Request, and in keeping with the Agency’s recent practice regarding the determination that da Vinci Surgical Systems which cost less than \$2,000,000.00 are not subject to CON Section Review and do not require a CON, Mission respectfully requests that the Agency confirm in writing at its earliest opportunity that Mission’s acquisition of an additional da Vinci Surgical System is not subject to further CON Section review and does not require a CON.

Please let us know if you have any questions regarding this request.

Sincerely,


Kenneth L. Burgess

² Mission acknowledges that medical equipment which costs less than \$2,000,000.00 may also qualify as a new institutional health service under other provisions of the CON Statute, such as N.C. Gen. Stat. § 131E-176 (7a) (governing diagnostic centers). The da Vinci Surgical System being acquired by Mission does not fall within the ambit of that statutory provision or any other provision of the CON Statute defining “new institutional health services.”

³ Mission does not believe that an Exemption Request is the appropriate vehicle for obtaining confirmation that da Vinci Surgical Systems are not subject to CON Section review because they are not the subject of a statutory exemption from provisions of the CON Statute that would otherwise make them “new institutional health services.” As a result, Mission is requesting a No Review Determination in this case.

