

JOSH STEIN • Governor

DEVDUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

May 28, 2025

William Maddrey wmaddrey@bakerdonelson.com

No Review

Record #: 4784

Date of Request: May 15, 2025 Facility Name: Mission Hospital

FID #: 943349

Business Name: MH Mission Hospital, LLLP

Business #: 3045

Project Description: Acquisition of a da Vinci Dual Xi Surgical System

County: Buncombe

Dear Mr. Maddrey:

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 representation in your request and 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. As a reminder, it is unlawful to offer or develop a new institutional health service without first obtaining a certificate of need. The Department reserves the right to impose sanctions, including civil penalties and the revocation of a license, upon any entity that offers or develops a new institutional health service without first obtaining a certificate of need.

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

Sincerely,

Ena Lightbourne, Project Analyst

Micheala Mitchell

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



2235 GATEWAY ACCESS POINT SUITE 220 RALEIGH, NORTH CAROLINA 27607

WWW.BAKERDONELSON.COM

WILLIAM F. MADDREY Direct Dial: 984-844-7922 Direct Fax: 919-338-7696

E-Mail Address: wmaddrey@bakerdonelson.com

May 15, 2025

VIA EMAIL

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

Micheala Mitchell, Chief 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 Ms. Mitchell:

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 convert the capital lease and own outright a DaVinci Surgical System currently located in operating room ("OR") 27 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 DaVinci 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") for the DaVinci System.

Project Description

In November of 2023, Mission acquired by capital lease a da Vinci Dual Xi Surgical System. This represented Mission's seventh (7th) da Vinci surgical robotics system. Mission obtained the seventh da Vinci surgical robotics system under a pay per use lease agreement. As such the acquisition did not constitute a new institutional health service and was not subject to CON approval.

Mission now intends to buy out the current capital lease and purchase the da Vinci Xi System outright at a cost of \$1,979,500.00. See Attachment 1 (Projected Capital Cost Form). See also, Attachment 2 (Statement of Mission Hospital Chief Operating Officer) and Attachment 3 (Amendment to the Transaction Agreement), the updated project cost.

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

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*, 205 N.C. App. 35, 696 S.E.2d 163 (2010).

acquisition by the CON Section is required and Mission is not required to obtain a CON before purchasing 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 conversion of the capital lease of its existing 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 4 (excerpt).**
- 2. March 16, 2020, approval of a No Review Request to acquire a da Vinci Surgical System by Rex Hospital, Inc. See Attachment 5 (excerpt).
- 3. August 31, 2021, approval of an Exemption Request to acquire a da Vinci Surgical System by Novant New Hanover Regional Medical Center. See Attachment 6 (excerpt).
- 4. April 25, 2024, approval a No Review Request to acquire a da Vinci Surgical System by Maria Parnham Health. **See Attachment 7 (excerpt).**
- 5. July 31, 2024, approval of a No Review Request to acquire a da Vinci Surgical System by Wataugu Medical Center. **See Attachment 8 (excerpt).**
- 6. February 14, 2025, approval of a No Review Request to acquire a da Vinci Surgical System by North Carolina Baptist Hospital. **See Attachment 9 (excerpt).**
- 7. March 4, 2025, approval of a No Review Request to acquire a da Vinci Surgical System by North Carolina Baptist Hospital. **See Attachment 10 (excerpt).**

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.

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."

Micheala	Mitchell
Page 4	

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

Sincerely,

William F. Maddrey

Willi f. Madding

Attachments

Projected Capital Cost Form

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	\$1,850,000.00
Non-Medical Equipment	\$0.00
Furniture	\$0.00
Consultant Fees (specify)	\$0.00
Financing Costs	\$0.00
Interest during Construction	\$0.00
Other (specify) (Sales Tax)	\$129,500.00
Total Capital Cost	\$1,979,500.00

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINE	EK
I certify that, to the best of my knowledge, the projected complete and correct.	capital cost for the proposed project is
N/A	Date Signed:
Signature of Licensed Architect or Engineer	
CERTIFICATION BY AN OFFICER OR AGENT FOR THE PRO I certify that, to the best of my knowledge, the projected to is complete and correct and that it is our intent to carry ou	otal capital cost for the proposed project
Wyatt Chocklett Wyatt Chocklett (May 9, 2025 16:35 EDT)	Date Signed:
Signature of Officer/Agent	

Wyatt Chocklett Chief Operating Officer

STATEMENT OF WYATT CHOCKLETT

- 1. I am the Chief Operating Officer for MH Mission Hospital, LLLP ("Mission"). I am personally familiar with Mission Hospital's plan to acquire an additional DaVinci Surgical System which will be installed in operating room 27 in the main Mission OR suite on Mission's main campus, license number H0036. I make this statement in support of Mission's No Review Determination Request to the N.C. Certificate of Need Section.
- 2. As part of my duties as Chief Operating Officer, I am responsible for the oversight of all operations for Mission Hospital, which includes the surgical program.
- 3. I am personally familiar with the proposed project which involves the acquisition of a seventh DaVinci Surgical System by Mission to be located in OR 27.
- 4. Under pain of perjury, I certify that the total costs of the project are approximately ONE MILLION, NINE HUNDRED SEVENTY-NINE THOUSAND, FIVE HUNDRED DOLLARS (\$ 1,979,500.00).
- 5. Furthermore, as part of this project, Mission Hospital will not acquire any new major medical equipment, increase total bed capacity, increase total operating room capacity or develop any other new institutional health services described in N.C. Gen. Stat. §131E-176 (16).

This the 9th day of May, 2025.

Wyatt Chocklett (May 9, 2025 16:35 EDT)

WYATT CHOCKLETT Chief Operating Officer MH Mission Hospital, LLLP

Amendment to the Transaction Agreement

This amendment (the "Amendment ") is made and entered into as of **the date of the last signature below** (the "Amendment Effective Date") by and between **Intuitive Surgical, Inc.,** a Delaware corporation, with its principal place of business located at 1266 Kifer Road, Sunnyvale, CA 94086 ("Intuitive") and **Mission Hospital** located at 509 Biltmore Ave, Asheville, North Carolina 28801-4690 ("Customer" or "Participant" or "Lessee").

WHEREAS, Intuitive and Lessee have entered into a Transaction Agreement dated November 8, 2023 (reference 42004569) (the "Lease Agreement") and its associated Use, License, and Service Agreement dated September 20, 2023 (reference 42004574), between Intuitive and HCA Management Services, L.P. ("ULSA") for the da Vinci SP® Single Console System, serial number SP0269 ("System") and associated equipment (collectively, "Equipment"); and

WHEREAS, Customer wishes to purchase the Equipment.

NOW, THEREFORE, in consideration of the foregoing and of the mutual promises and covenants hereinafter expressed, and for other valuable consideration, the receipt and adequacy of which the parties hereby acknowledge, the parties agree to amend the Lease Agreement as follows:

- 1. **Buyout Amount.** Intuitive and Lessee agree Lessee may purchase the Equipment (including System, serial number **SP0269**). Lessee agrees to purchase the Equipment for the buyout amount of \$1,850,000.00 ("Buyout Amount"). Lessee remains responsible for any open invoices for the Lease Agreement and the Buyout Amount is contingent upon Intuitive receiving Lessee's payment for those open invoices.
- 2. **Payment Terms.** Upon the date of the last signature below, Intuitive will issue Lessee invoice(s) totaling the amount of \$1,850,000.00 for the Equipment, and \$129,500.00 in sales tax for the Equipment. Lessee will pay the invoiced amount not later than thirty (30) days after the date of invoice(s). Interest will accrue from the date on which payment is due, at an annual rate of twelve percent (12%) or the maximum rate permitted by applicable law, whichever is lower.
- 3. **Title.** Subject to Section 4 below, title to the System with serial number SP0269, will transfer to Lessee upon the date of the last signature below.
- 4. **Security Interest.** Intuitive will retain a security interest in the System until payment of the full Buyout Amount has been received by Intuitive. Lessee will perform all acts Intuitive reasonably determines are necessary or appropriate to perfect and maintain the security interest. If Lessee defaults in its payments for the Buyout Amount, Intuitive has the right, without liability to Lessee, to reclaim the System.
- 5. **Service.** Lessee's Service plan will continue as per the ULSA, specifically, the dvComplete Care Plan at \$100,000.00 per year, which Lessee continues to be bound to purchase.

BOTH PARTIES HAVE READ, UNDERSTOOD, and agreed to be bound by the terms and conditions of this Amendment and execute this Amendment as of the Amendment Effective Date.

If this Amendment is not signed by both parties and returned to Intuitive on or before JUNE 28, 2025, the terms will be subject to change.

ACCEPTED BY:		ACCEPTED BY:
Intuitive Surgical, Inc.		Mission Hospital
Signature:	Alonso Torres	Ву:
Email:	Alonso.Torres@intusurg.com	Name:
Title:	Sr. Manager, Contract Administration	Title:
Company:	Intuitive Surgical, Inc.	e-mail:
		c-man
		Data

Customer Name: Mission Hospital Agreement: 42008368

Rev: US Rev 1



ROY COOPER • Governor

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,

cc:

Tanya M. Saporito

Project Analyst

Martha J. Frisone

Chief

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

Waller, Martha K

From:

dlegarth@nc.rr.com

Sent:

Tuesday, November 26, 2019 5:59 PM

To:

Tanya, Saporito; Waller, Martha K

Cc:

'Nancy O'Dacre'

Subject:

[External] Letters of CON Exemption

Attachments:

NHRMC daVinci Acquisition Letter.pdf; NHRMC SENCA Acquisition Letter.pdf

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report spam@nc.gov

Good Evening,

Attached please find two Letters of CON Exemption. One letters pertains to the acquisition of limited assets of SENCA Properties, LLC and the other letter pertains to the acquisition of a DaVinci surgical robot.

Have a great Thanksgiving!

David Legarth



Mail Address:

P.O. Box 1936 Apex, NC 27502 FedEx/UPS Address:

108 Curely Maple Court

Apex, NC 27502

Phone:

(919)244-7609





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

NHRM (943372

NR12 3174

Bus 1308



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. McKilli

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





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,

Elizabeth Runyon

Elizabeth Runyon

System Director of Regulatory Affairs & Special Counsel

UNC Health Care

INTUÎTIVE.

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

Quote Details			Company Information
Quote ID	131032.0	Hospital Name	Rex Healthcare
Quote Date	1/28/2020	SF ID / IDN Affiliation	13742/UNC Health Care
Valid Until	3/16/2020	Address	4420 Lake Boone Trail
Sales Rep	Ryan Carlson	City, State, Zip	Raleigh, NC, 27607-6599
Phone Number	1(727) 698-5339	Contact Name	
Email	Ryan.Carlson@intusurg.com	Telephone	

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

Items		454	ec. Sensolves topoexonester in a cooper exonocyclopal demonstratory energy por • References to the cooper of the		\$33594300 Ceses 2	
Part Number	Qty	Iten	n	Price	Discount	Subtotal
da Vinci Syster	ns		,			
2	1	One Syst Vinc Trair	/inci Xi® Single Console System (1): da Vinci Xi System Surgeon Console One (1): da Vinci Xi em Patient Cart One (1): da Vinci Xi System Vision Cart da ix I System Documentation da Vinci Xi System Software ning Instrument Starter Kit Accessory Starter Kit Drapes Vision ipment (All Kits subject to change without notice)	\$1,900,000.0	0 \$1,175,000.00	\$725,000.00
Freight				ST	No. of the second secon	
	1	Syst ME,	em Freight - East (AL, CT, DC, DE, FL, GA, IN, KY, MA, MD, MI, MS, NC, NH, NJ, NY, OH, PA, RI, TN, SC, VA, VT, WV)	\$10,000.0	0 \$0.00	\$10,000.00
Total				\$735,000.00		
Service						
Part Number	Q	ty	Item		rice	Subtotal
	1		Da Vinci Xi® dVComplete Care Service Plan (single console) Years 2-5, per year		\$328,000.00	\$328,000.00
	1		Year One System Service (Included in System Fee unless an amount is listed)		\$328,000.00	\$328,000.00

Leasing Terms

Leasing options are available through Intuitive Surgical on systems and select upgrades. Please contact your Intuitive representative for additional details.

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

Waller, Martha K

From:

Runyon, Elizabeth < Elizabeth.Runyon@unchealth.unc.edu>

Sent:

Thursday, March 5, 2020 9:48 AM

To: Cc: Mckillip, Mike Waller, Martha K

Subject:

[External] Rex No Review Request

Attachments:

2020.3.5 Rex daVinci No Review.pdf; Exhibit 1 - Quote 131032 Rex Healthcare.pdf

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report spam@nc.gov

Mike,

Please see the attached No Review request for Rex Hospital. Let me know if you have any questions. Thank you!

Elizabeth

Elizabeth Frock Runyon

System Director of Regulatory Affairs and Special Counsel UNC Health
211 Friday Center Drive, Chapel Hill, NC 27517
p (984) 215-3622
elizabeth.runyon@unchealth.unc.edu

---- Confidentiality Notice ----

The information contained in (or attached to) this electronic message may be legally privileged and/or confidential information. If you have received this communication in error, please notify the sender immediately and delete the message.



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.

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

Sincerely,

Tanya M. Saporito

Micheala Mits. 10

Dange Mesont

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



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.

Sincefely,

Kristy Hubard

Chief Strategy Officer

Novant Health New Hanover Regional Medical Center



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

Micheala Mitchell

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

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 (140).

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.

10

Sincerely,

Bert Beard Chief Executive Officer Maria Parham Health

A Duke Lifepoint Hospital



ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

July 31, 2024

Deanna S. Mool dsmool@apprhs.org

No Review

Record #: 4491

Date of Request: June 19, 2024

Facility Name: Watauga Medical Center

FID #: 933533

Business Name: Watauga Medical Center, Inc.

Business #: 2040

Project Description: Acquire an Intuitive da Vinci V Surgical Robot System

County: Watauga

Dear Ms. Mool:

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 Mitroco

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





June 19, 2024

VIA ELECTRONIC MAIL

Ms. Ena Lightbourne
Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human services

RE: No Review Determination -

Dear Ms. Lightbourne:

On behalf of Watauga Medical Center, Inc. (WMC) this letter serves as notice to the Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section ("Agency") that WMC intends to acquire an Intuitive da Vinci V surgical robot to be located in the Watauga Medical Center hospital surgical suite in Boone, North Carolina. The details regarding the DaVinci V robot system are set forth below.

The purpose of this letter is to request that the Agency issue a "No Determination Letter" indicating the acquisition of the da Vinci system is not subject to CON Section review and does not require that the Hospital obtain a certificate of need ("CON").

The da Vinci V system cost will be \$1,875,000 via a capital lease. The equipment requires no modifications to the building and there are no constructions costs involved. Further, the addition does not constitute a new institutional health service.

Sincerely,

Deanna S. Mool Chief Legal Officer



JOSH STEIN • Governor

DEVDUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

February 14, 2025

Nicole Moore

nsmoore@wakehealth.edu

No Review

Record #: 4712

Date of Request: February 11, 2025

Facility Name: North Carolina Baptist Hospital

FID #: 943495

Business Name: North Carolina Baptist Hospital

Business #: 1819

Project Description: Acquire an Intuitive da Vinci Xi robot to be located in outpatient surgery center on NCBH

main campus

County: Forsyth

Dear Ms. Moore:

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 representation in your request and 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. As a reminder, it is unlawful to offer or develop a new institutional health service without first obtaining a certificate of need. The Department reserves the right to impose sanctions, including civil penalties and the revocation of a license, upon any entity that offers or develops a new institutional health service without first obtaining a certificate of need.

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

Sincerely,

Yolanda W. Jackson Yolanda W. Jackson

Micheala Mitchell

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



Medical Center Blvd Winston-Salem, NC 27157 O: 336.716.6968 nsmoore@wakehealth.edu

February 11, 2025

Ms. Micheala Mitchell, Chief Ms. Yolanda Jackson, Project Analyst Healthcare Planning and Certificate of Need Section Division of Health Service Regulation 809 Ruggles Drive Raleigh, NC 27603

Re: No Review Determination for Acquisition of da Vinci Robot

Dear Ms. Mitchell and Ms. Jackson,

This letter serves as notice to the Department of Health & Human Services, Division of Health Service Regulation, Certificate of Need Section ("Agency") that North Carolina Baptist Hospital (NCBH) intends to acquire an Intuitive da Vinci Xi robot to be located on its West Campus Surgery Center ("Cloverdale"), which is an outpatient surgery center to be located on the main campus of NCBH in Winston-Salem, NC (Forsyth County). The details regarding the da Vinci Xi robot system are set forth below.

The purpose of this letter is to request that the Agency issue a "No Review" determination indicating acquisition of the da Vinci Xi system is not subject to CON Section review and does not require that NCBH obtain a certificate of need ("CON").

The total capital cost for the proposed acquisition is \$2,000,000 (see Exhibit A for the vendor quote). These costs include all expenses associated with the equipment and renovations. The addition of the da Vinci Xi system does not constitute a new institutional health service. Therefore, NCBH respectfully requests approval of no review determination for the proposed project.

Please let me know if you have any questions or if additional information is needed.

Sincerely,

Nicole Moore

Director, Core Market Growth & Business Development

Atrium Health Wake Forest Baptist

Nicola Moore



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DEVDUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

March 4, 2025

Nicole Moore

nsmoore@wakehealth.edu

No Review

Record #: 4711

Date of Request: February 11, 2025

Facility Name: North Carolina Baptist Hospital

FID #: 943495

Business Name: North Carolina Baptist Hospital

Business #: 1819

Project Description: Acquire an Intuitive da Vinci Xi robot to be located in NCBH's main campus

hospital surgical suite

County: Forsyth

Dear Ms. Moore:

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 representation in your request and 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. As a reminder, it is unlawful to offer or develop a new institutional health service without first obtaining a certificate of need. The Department reserves the right to impose sanctions, including civil penalties and the revocation of a license, upon any entity that offers or develops a new institutional health service without first obtaining a certificate of need.

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

Yolanda W. Jackson Project Analyst

Yolanda W. Jackson

Micheala Mitta. 10

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



Medical Center Blvd Winston-Salem, NC 27157 O: 336.716.6968 nsmoore@wakehealth.edu

February 11, 2025

Ms. Micheala Mitchell, Chief Ms. Yolanda Jackson, Project Analyst Healthcare Planning and Certificate of Need Section Division of Health Service Regulation 809 Ruggles Drive Raleigh, NC 27603

Re: No Review Determination for Acquisition of da Vinci Robot

Dear Ms. Mitchell and Ms. Jackson,

This letter serves as notice to the Department of Health & Human Services, Division of Health Service Regulation, Certificate of Need Section ("Agency") that North Carolina Baptist Hospital (NCBH) intends to acquire an Intuitive da Vinci Xi robot to be located in NCBH's main campus hospital surgical suite. The details regarding the da Vinci Xi robot system are set forth below.

The purpose of this letter is to request that the Agency issue a "No Review" determination indicating acquisition of the da Vinci Xi system is not subject to CON Section review and does not require that NCBH obtain a certificate of need ("CON").

The total capital cost for the proposed acquisition is \$2,000,000 (see Exhibit A for the vendor quote). These costs include all expenses associated with the equipment and renovations. The addition of the da Vinci Xi system does not constitute a new institutional health service. Therefore, NCBH respectfully requests approval of no review determination for the proposed project.

Please let me know if you have any questions or if additional information is needed.

Sincerely,

Nicole Moore

Nicola Moore

Director, Core Market Growth & Business Development

Atrium Health Wake Forest Baptist

 From:
 Mitchell, Micheala L

 To:
 Stancil, Tiffany C

 Cc:
 Lightbourne, Ena

Subject: FW: [External] Request for No Review Determination da Vinci System Mission Hospital

Date: Thursday, May 15, 2025 11:03:52 AM

Attachments: Mission Hospital No Review Determination Request daVinci System #7 with attachments 4910-3811-5134 v.1.pdf

Tiffany, would you mind logging this and assigning it to Ena?

Thanks,

Micheala

Micheala Mitchell, JD

NC Department of Health and Human Services

Division of Health Service Regulation

Section Chief, Healthcare Planning and CON Section
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center

Raleigh, NC 27699-2704

Office: 919 855 3879

Micheala.Mitchell@dhhs.nc.gov

From: Maddrey, William <wmaddrey@bakerdonelson.com>

Sent: Thursday, May 15, 2025 10:49 AM

To: Mitchell, Micheala L < Micheala. Mitchell@dhhs.nc.gov>; Lightbourne, Ena

<ena.lightbourne@dhhs.nc.gov>

Cc: Stauffer, Iain <istauffer@bakerdonelson.com>

Subject: [External] Request for No Review Determination da Vinci System Mission Hospital

You don't often get email from wmaddrey@bakerdonelson.com. Learn why this is important

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Micheala and Ena,

I hope you both are doing well. Please see the attached No Review Request that I am submitting on behalf of my client Mission Hospital. Please let me know if you need any additional information.

William F. Maddrey

Associate

Baker, Donelson, Bearman, Caldwell & Berkowitz, PC 2235 Gateway Access Point, Suite 220 Raleigh, NC 27607

Direct: 984.844.7922 Cell: 919.271.8582

wmaddrey@bakerdonelson.com

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