

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

December 30, 2024

Elizabeth Kirkman

Elizabeth.kirkman@atriumhealth.org

No Review

Record #: 4676

Date of Request: December 19, 2024
Facility Name: Atrium Health Cabarrus

FID #: 943049

Business Name: The Charlotte-Mecklenburg Hospital Authority

Business #: 1770

Project Description: Retain the Intuitive Surgical, Inc. fixed da Vinci Surgical Robot model da Vinci Xi Dual

Console SK2786 that will be replaced

County: Cabarrus

Dear Ms. Kirkman:

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,

Gregory F. Yakaboski, 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

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

Ms. Micheala Mitchell, Chief Healthcare Planning and Certificate of Need Section Division of Health Service Regulation N.C. Department of Health & Human Services 809 Ruggles Drive Raleigh, NC 27603

RE: Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Atrium Health Cabarrus ("AH Cabarrus") to Replace and Retain daVinci Surgical Robot Equipment

Dear Ms. Mitchell:

The Charlotte-Mecklenburg Hospital Authority d/b/a Atrium Health Cabarrus ("AH Cabarrus"), seeks to acquire a da Vinci Xi dual console surgical robot ("Replacement Equipment").

The Replacement Equipment will replace a da Vinci Xi dual console ("Existing Equipment") that was originally acquired in 2019. The Existing Equipment is currently housed in the surgical suite on the first floor of the Surgery Center Building on the main campus of AH Cabarrus located at 920 Church Street North, Concord, NC 28025. The Replacement Equipment will also be located in the same surgical suite on the main campus (see Attachment A).

The purpose of this letter is to provide the Agency with notice and to request a determination that AH Cabarrus's purchase of the Replacement Equipment is exempt from Certificate of Need ("CON") review under the replacement equipment exemption provisions contained in NCGS § 131E-184(a)(7). AH Cabarrus is also seeking approval to retain the Existing Equipment as a non-reviewable project due to the fair market value of the existing equipment being less than the current threshold for major medical equipment as defined in NCGS § 131E-176(14o).

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of "replacement equipment," defined in NCGS § 131E-176(22a) as follows in the CON law:

"Replacement equipment" means equipment that costs less than three million dollars (\$3,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. In determining whether the replacement equipment costs less than three million dollars (\$3,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement 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. Beginning September 30, 2023, 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.

Under the provisions found at NCGS § 131E-184(f)(1)-(3), the CON law provides:

- (f) The Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the monetary threshold set forth in G.S. 131E-176(22a) if all of the following conditions are met:
 - (1) The equipment being replaced is located on the main campus.
 - (2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
 - (3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

The term "main campus" was defined in Session Law 2013-360, Section 13G.3(a) (codified N.C. Gen. Stat. 131E-176(14n)) as follows:

- (14n) "Main campus" means all of the following for the purposes of G.S. 131E-184(f) and (g) only:
 - a. The site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building.
 - b. Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

The Existing Equipment is currently located in the surgical suite on the first floor of the Surgery Center Building on the main campus of AH Cabarrus. The main hospital building, located at 920 Church Street North in Concord, is the site from which AH Cabarrus exercises financial and administrative control over the entire facility. AH Cabarrus's Facility Executive's office is located on the first floor of the main hospital building. Please see a copy of AH Cabarrus's hospital license in Attachment B.

In addition to the foregoing, AH Cabarrus's proposal qualifies for this exemption based on the following information:

A. Cost of the Replacement Equipment

The purchase price of the Replacement Equipment is \$2,438,500 (excluding discounts but including freight). There is no renovation required to install the Replacement Equipment, so the quote equals the total cost of this project. Attachment C provides the quote for the Replacement Equipment.

B. Equipment Being Replaced is Located on the Main Campus

The Existing Equipment is currently located in the surgical suite on the first floor of the Surgery Center Building on AH Cabarrus's main campus. The Replacement Equipment will be located in the same surgical suite.

C. Certificate of Need Issued for Equipment Being Replaced

This proposal also fits within the exemption criterion in Section 131E-184(f)(2). No certificate of need was required to acquire the Existing Equipment because the fair market value ("FMV") of the equipment was less than \$750,000, which was the "major medical equipment" threshold under N.C.G.S 131E-176(14o) at that time.

D. Comparable Equipment

The CON rule codified as 10A N.C.A.C. 14C.0303 (the "Regulation") defines "comparable medical equipment" in subsection (c) as follows:

"Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

The Existing Equipment has been used to perform minimally invasive surgical procedures. Although it possesses some expanded capabilities due to technological improvements, AH Cabarrus intends to use the Replacement Equipment for substantially the same procedures for which it currently uses the Existing Equipment (see Attachment D for the Equipment Brochure). The Replacement Equipment is therefore "comparable medical equipment" as defined in Subsection (c).

Furthermore, AH Cabarrus does not intend to increase patient charges or per procedure operating expenses within the first 12 months after equipment acquisition. For further equipment comparison, please refer to Attachment E, the Equipment Comparison Chart.

Subsection (d) of the regulation further provides:

- (1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
- (2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
- (3) the acquisition of the equipment does not result in more than a 10.0 percent increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

The Replacement Equipment will meet all three of tests set out in Subsection (d). The Replacement Equipment satisfies the technology and functionality tests in Subsection (1) and (2) as discussed above and identified in the Comparison Chart (Attachment E). Moreover, AH Cabarrus represents the use of the Replacement Equipment will not result in the types of expense or charge increases described in Subsection (d)(3).

The Existing Equipment is currently in operation and from December 2023 to November 2024 there were 548 procedures performed on the Existing Equipment.

E. Existing Equipment

At the time of the acquisition of the Existing Equipment the purchase price was \$725,000 (See Attachment F). Since the fair market value ("FMV") of the Existing Equipment was significantly less than the current CON reviewability threshold for "major medical equipment" under N.C.G.S 131E-176(140) of \$2,059,600 five years ago in 2019, the current FMV of the Existing Equipment must also be less than \$2,059,600. Given that the value of this equipment is less than the reviewability threshold for "major medical equipment", AH Cabarrus proposes to retain the Existing Equipment in its current location in the surgical suite on the first floor of the Surgery Center Building on the main campus of AH Cabarrus.

CONCLUSION:

Based on the foregoing information, AH Cabarrus hereby requests that the Agency provide a written response confirming that the acquisition and relocation of the Replacement Equipment and the retention of the Existing Equipment described herein is exempt from CON review. If the Agency needs additional information to assist in its consideration of this request, please let us know.

Thank you for your consideration of this notice.

Sincerely,

Elizabeth V. Kirkman Assistant Vice President

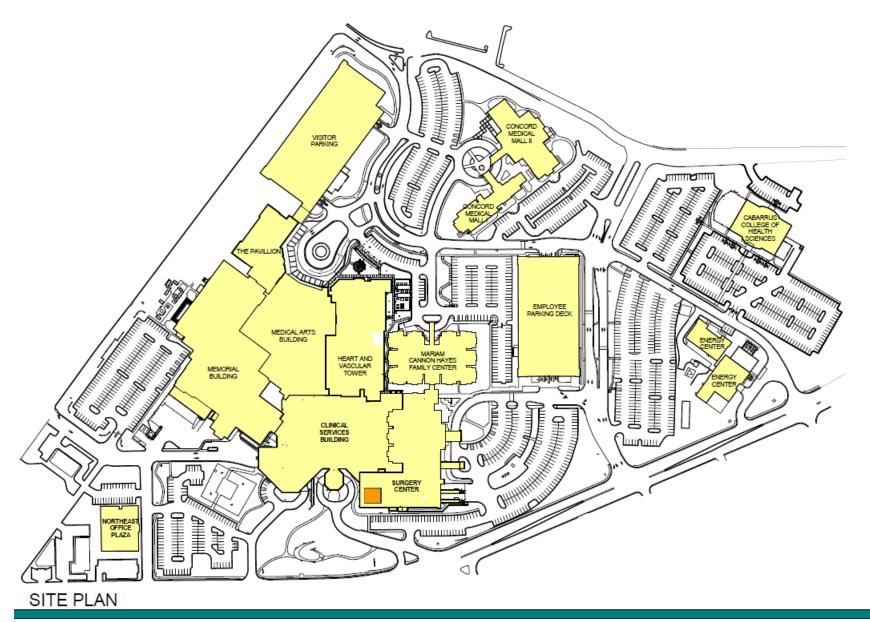
Core Market Growth Business Development

Elegabeth V, Kerkenain

Atrium Health

Attachments





Atrium Health

Atrium Health Cabarrus



State of Aurth Carolina Department of Health and Human Services Division of Health Service Regulation

Effective January 1, 2024, this license is issued to

The Charlotte-Mecklenburg Hospital Authority

to operate a hospital known as

Atrium Health Cabarrus

located at Concord, NC, Cabarrus County.

This license is issued subject to the statutes of the State of North Carolina, is not transferable and shall remain in effect until amended by the issuing agency.

Facility ID: 943049 License Number: H0031

Bed Capacity:457

General Acute: 447 Psych: 10

Dedicated Inpatient Surgical Operating Rooms: 4 Shared

Dedicated Ambulatory Surgical Operating Rooms: 0

Shared Surgical Operating Rooms: 15

Dedicated Endoscopy Rooms: 6

License Categories:

.1100 Partial Hospitalization, .3500 Outpatient Facilities, .5200 Dedicated Inpatient Unit for mental disorders,

Authorized by:

Secretary, N.C. Department of Health and Human Services



Director, Division of Health Service Regulation



INTUÎTIVE

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

Quote Details Company Information

Quote ID	Q-00065905
Quote Date	11/13/2024
Valid Until	12/31/2024
Sales Rep	Matthew Kilmartin
Phone Number	+1-616-970-1538
Email	matthew.kilmartin@intusurg.com

Hospital Name	Atrium Health Cabarrus
SF ID/IDN Affiliation	13682/Atrium Health
Address	920 Church St North
City, State, Zip	Concord, North Carolina, 28025-2983
Contact Name	
Telephone	

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

Part Number	Qty	Item	Price	Discount	Subtotal	
Systems	Systems					
	1	da Vinci Xi® Dual Console SystemOne (2): 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)	\$ 2,350,000.00	\$ 125,000.00	\$ 2,225,000.00	
Upgrades						
	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)	\$ 13,500.00	\$ 2,750.00	\$ 10,750.00	
Others						
	1	MULTI-SYSTEM DISCOUNT	\$ 0.00	\$ 0.00	\$ (200,000.00)	
Total					\$ 2,085,750.00	

Part Number	Months	Item	Price	Discount	Annual Service Fee
Service					
	12	da Vinci Xi-Dual Console-Human Use (Systems)-SERVICE PLAN : DVCOMPLETE CARE-Warranty (Included)	\$ 0.00	\$ 0.00	\$ 0.00
	48	da Vinci Xi-Dual Console-Human Use (Systems)-SERVICE PLAN : DVCOMPLETE CARE-After Warranty Service (Annual)	\$ 179,000.00	\$ 19,000.00	\$ 160,000.00

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 handlingcharge 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™ Dual Console System (Firefly™ Fluorescence Imaging Enabled)

Two (2): da Vinci® Xi™ System Surgeon Consoles

One (1): da Vinci® Xi™ System Patient Cart

One (1): da Vinci® Xi™ System Vision Cart

One (1): Integrated E-200 Generator

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 Force Traid 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 Tray

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)





EQUIPMENT COMPARISON – AH Cabarrus da Vinci Robot Replacement

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, etc.)	da Vinci Surgical Robot	da Vinci Surgical Robot
Manufacturer	Intuitive Surgical, Inc.	Intuitive Surgical, Inc.
Model name/number	da Vinci Xi Dual Console	da Vinci Xi Dual Console SystemOne
Other method of identifying the equipment (e.g., Serial Number, VIN #)	SK2786	Not Available Until Installed
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2019	2024
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project	\$725,000	\$2,438,500
Total cost of the equipment	\$725,000	\$2,438,500
Location of the equipment	AH Cabarrus Surgery Center Building, Surgical Suite, Level 01	AH Cabarrus Surgery Center Building, Surgical Suite, Level 01
Document that the existing equipment is currently in use	Existing equipment performed 548 procedures from Dec 2023 to Nov 2024	NA
Will the replacement equipment result in any increase in the average charge per procedure ?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	NA
Will the replacement equipment result in any increase in the average operating expense per procedure?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment	Minimally Invasive Surgical Procedures	NA
Type of procedures the replacement equipment will perform	NA	Minimally Invasive Surgical Procedures



Amendment to the Sales Agreement

This Amendment to the Service Agreement (the "Amendment") is made and entered into as of **June 24, 2019** (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 **Carolinas Medical Center** on behalf of its facility **Carolinas Medical Center-NorthEast** located at 920 Church Street North, Concord, North Carolina 28025-2983 ("Customer").

WHEREAS, Intuitive and Carolinas Medical Center entered into a Sales Agreement with the Effective Date of December 15, 2017, agreement number MA-831-2017 (the "Sales Agreement") and a Service Agreement with the Effective Date December 15, 2017, agreement number MA-831-2017 (the "Service Agreement"), and

WHEREAS, Customer now wishes to purchase a System from Intuitive under the same terms of that Sales Agreement, and Intuitive wishes to sell such System to Customer under the terms and conditions of the Sales Agreement, and as set forth herein.

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 Sales Agreement as follows:

1. General.

1.1 Customer will purchase Hardware and license Software for a System under the terms of this Amendment. The System purchased hereunder is deemed a separate transaction from any other purchases by Customer. The System purchased hereunder will be delivered, accepted and paid for under the terms and conditions as set forth in this Amendment.

2. Definitions.

2.1 Notwithstanding anything to the contrary in Section 2.1 ("Definitions"), for purposes of this Amendment:

"System" means the items comprising the da Vinci® Surgical System specified in Attachment 1 to this Amendment consisting of certain hardware components ("Hardware"), software program elements ("Software") and related manuals, labeling, instructions for use, notifications or other documentation ("Documentation"), that Customer may receive, purchase and license under this Sales Agreement. If Customer purchases multiple Systems under this Sales Agreement, all references to "System" or "System(s)" apply to each System sold and licensed. Each System purchased is a separate transaction to be delivered, accepted, and paid for separately.

"Initial Term" means the period commencing as of the Amendment Effective Date and will continue for a period of five (5) years from Acceptance of the System purchased under this Amendment.

3. Intuitive's Obligations.

- 3.1 Notwithstanding anything to the contrary in Section 2.2(a) and 2.2(b) ("Delivery Date" and "Delivery Terms") of the Sales Agreement, for purposes of this Amendment, the Delivery Date for the System purchased hereunder shall be on or before **June 30, 2019.** Further, for the avoidance of doubt, Acceptance of the System purchased hereunder shall be upon delivery to Customer's designated location. Title passes to the Customer on Acceptance. For purposes of this Amendment, Intuitive will deliver the System purchased hereunder to Customer's designated location, using a carrier selected by Intuitive and for the fees set forth in Section 4 below.
- 3.2 Notwithstanding anything to the contrary in Section 2.6 ("System Warranty and Disclaimers") of the Sales Agreement, for the purposes of this Amendment, the period for the System warranties are for the period specified on Attachment 1.

4. Price and Payment Terms for the System.

4.1 Price Terms. Notwithstanding anything to the contrary in the Sales Agreement, for purposes of this Amendment and the System purchased hereunder, Exhibit A is amended to include the additional fees for the System purchased hereunder. Intuitive makes no representation with regard to Certificate of Need requirements for this purchase. It is Customer's responsibility to determine whether this purchase complies with Customer's State's Certificate of Need laws and what Certificate of Need filing, if any, needs to be made with regard to this purchase.

Description	Qty	Delivery Date	Price	Delivery Charge
da Vinci® Xi TM Dual Console System (Firefly TM	1	On or before June	\$725,000.00	Waived
Fluorescence Imaging Enabled)		30, 2019		
da Vinci® Xi TM Integrated Table Motion Upgrade	1	See Below**	\$0.00	Pre-Pay & Add

^{*}Subject to availability, Instruments and Accessories are subject to the Terms of the da Vinci EndoWrist Instrument & Accessory Catalog as if such Terms were contained in this Amendment. Shipment of Instruments and Accessories listed above will be FOB origin. Some

Instruments and Accessories listed above may require Customer's completion of the advanced instrument training verification prior to shipment.

- 4.2 Payment Terms for the System. Notwithstanding anything to the contrary in the Sales Agreement, for purposes of this Amendment and the System purchased hereunder, upon Acceptance, Intuitive will deliver an invoice to Customer for amounts due under this Amendment for the System. Customer will pay the invoiced amount not later than thirty (30) days after the date of invoice. 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.
- 5. Notices.
 - Notwithstanding anything to the contrary in the Sales Agreement, for purposes of this Amendment, the following addresses apply to the System purchased hereunder:

Customer Ship-To:	Customer Bill-To:
Carolinas Medical Center - NorthEast	Carolinas Medical Center - NorthEast
920 Church Street North	920 Church Street North
Concord, NC 28025-2983	Concord, NC 28025-2983

6. Section 14.12 ("Data Use") of the Sales Agreement is deleted in its entirety and replaced with the following:

Data Use. Customer agrees that Intuitive and its affiliates within the Intuitive Surgical group of companies (collectively, "Intuitive") may collect data relating to the use of Intuitive products ("Data"). In some instances Data may be communicated via data gathering or transmission technology to Intuitive. In other instances, Intuitive may require Customer and Customer agrees to provide Data to Intuitive. Such Data may be used for a variety of purposes, including, but not limited to (1) providing support and preventative maintenance of Intuitive products, (2) improving Intuitive products or services, (3) ensuring compliance with applicable laws and regulations, and (4) providing a general resource for Intuitive's research and business development. Intuitive does not intend to collect protected health information (PHI) as defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) or analogous foreign patient privacy laws or regulations, as may be amended from time to time. In the event any Data communicated to Intuitive inadvertently contains PHI, Intuitive shall immediately notify Customer. Further, in the event any Data otherwise identifies an entity or individual, Intuitive will not use or share such Data with any third parties without the entity's or individual's written authorization, unless required by law or regulatory authorities. Intuitive shall only seek such authorization for an entity or individual after obtaining consent to do so from Customer, unless otherwise required by law or regulatory authorities. In the event this Agreement involves a service whereby Intuitive will receive Protected Health Information (as defined under the Health Insurance Portability and Accountability Act of 1996 and the regulations and official guidance promulgated thereunder), Intuitive will, at Customer's request, execute a mutually agreeable Business Associate Agreement. In addition, Intuitive agrees to immediately notify Customer if Intuitive anticipates it will have access to Protected Health Information as a result of activities done pursuant to this Agreement and, at Customer's request, enter into such mutually agreeable Business Associate Agreement.

7. Any capitalized terms used but not defined herein will have the meaning used in the Sales Agreement. Except as set forth above, all other terms and conditions of the Sales Agreement remain the same.

In witness whereof, the parties have caused this Amendment to be executed by their duly authorized representatives.

If this Amendment is not signed by both parties and returned to Intuitive on or before June 28, 2019, the terms will be subject to change.

Signature:	Marc Giuffrida (Jun 24, 2019)	By:
Email:	marc.giuffrida@intusurg.com	Naı
Title:	Director, Contract Administration	Titl
Company:	Intuitive Surgical, Inc	e-m
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<i>y U</i>		ъ.

ACCEPTED BY: Intuitive Surgical, Inc.

ACCEPTED BY: Carolinas Medical Center

ATTACHMENT 1

Intuitive will deliver the following System: da Vinci® XiTM Dual Console System (FireflyTM Fluorescence Imaging Enabled)

Two (2): da Vinci® XiTM System Surgeon Consoles

One (1): da Vinci® XiTM System Patient Cart

One (1) da Vinci® XiTM System Vision Cart

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

da Vinci® XiTM 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® XiTM Cleaning & Sterilization Kit

Warranty period: 90 days from Acceptance

Two (2) da Vinci $\ Xi^{TM}$ Instrument Release Kit (IRK)

Warranty period: 90 days from Acceptance

da Vinci® XiTM 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® XiTM Gage Pin

Three (3): Instrument Introducer

One (1): Box of 10: Tip Cover for Hot ShearsTM (MCS)

One (1): Pmed Cable, Covidien Force Traid ESU

Warranty period: 90 days from Acceptance

Drapes

Two (2): Pack of 20 da Vinci® XiTM Arm Drape

One (1): Pack of 20 da Vinci® XiTM Column Drape

Warranty period: 90 days from Acceptance

Vision Equipment:

Two (2): da Vinci® XiTM Endoscope with Camera, 8 mm 0 degree

Two (2): da Vinci® XiTM Endoscope with Camera, 8 mm 30 degree

Four (4): da Vinci® XiTM Endoscope Sterilization Tray

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

Training Instrument Starter Kit

One (1): Large Needle Driver

One (1): ProGraspTM Forceps

One (1): Maryland Bipolar Forceps

One (1): Hot ShearsTM (Monopolar Curved Scissors)

One (1): Tip-Up Fenestrated Grasper

One (1): MegaTM SutureCutTM Needle Driver

Warranty period: 90 days from Acceptance

(all kits subject to change without notice)

(rev 4/2015)

Intuitive Proprietary Information

Carolinas Medical Center – NorthEast

MA-831-2017 (CLM 408989)

24Jun2019

Page 3 of 3

Amendment to the Service Agreement

This Amendment to the Service Agreement (the "Amendment") is made and entered into as of **June 24, 2019** (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 **Carolinas Medical Center** on behalf of its facility **Carolinas Medical Center-NorthEast** located at 920 Church Street North, Concord, North Carolina 28025-2983 ("Customer").

WHEREAS, Intuitive and Carolinas Medical Center entered into a Sales Agreement with the Effective Date of December 15, 2017, agreement number MA-831-2017 (the "Sales Agreement") and a Service Agreement with the Effective Date December 15, 2017, agreement number MA-831-2017 (the "Service Agreement"), and

WHEREAS, Customer will purchase a System from Intuitive under an amendment to that Sales Agreement and wishes to purchase Service for such System under the same terms of that Service Agreement, and Intuitive wishes to sell such Service to Customer under the terms and conditions of the Service Agreement, and as set forth herein.

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 Service Agreement as follows:

- 1. Services.
 - 2.1 Obligation to purchase Services. Intuitive makes no representation with regard to Certificate of Need requirements for this purchase. It is Customer's responsibility to determine whether this purchase complies with Customer's State Certificate of Need laws and what Certificate of Need filing, if any, needs to be made with regard to this purchase. Customer agrees and acknowledges payment for the Service for years 1-5 shall not be excused by any contingencies including, but not limited to, Customer's internal practices, policies, or any state approvals.
 - 2.2 Fees

Service Type	Annual Service Fees
dV Complete Care Plan	Years 1-5 of the Initial Term:
	\$423,200.00 per year

2.3 Price and Payment Terms for Services

Intuitive will deliver to Customer an invoice for the annual Services fee thirty (30) days prior to the first anniversary of Acceptance and each subsequent anniversary of Acceptance throughout the Initial Term of the Agreement. Customer will pay the invoice for Services not later than thirty (30) days after the date of invoice. 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. After the Initial Term of the Agreement, and subject to mutual written agreement, annual Services may be renewed at Intuitive's then current list price.

- 3. Term.
 - 3.1 Notwithstanding anything to the contrary in Section 4 ("Term") of the Service Agreement, for purposes of this Amendment, the Initial Term for the System purchased hereunder shall commence as of the Amendment Effective Date and will continue until the fifth (5th) anniversary of the Acceptance Date for such System.
- 4. Any capitalized terms used but not defined herein will have the meaning used in the Service Agreement. Except as set forth above, all other terms and conditions of the Service Agreement remain the same.

In witness whereof, the parties have caused this Amendment to be executed by their duly authorized representatives.

If this Amendment is not signed by both parties and returned to Intuitive on or before June 28, 2019, the terms will be subject to change.

ACCEPTED BY: Intuitive Surgical, Inc.

Signature: Marc Giufrida (Jun 24, 2019)

Email: marc.giuffrida@intusurg.com

Title: Director, Contract Administration

Company: Intuitive Surgical, Inc

P0

ACCEPTED BY:	Carolinas	Medical	Center
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	Jim Olsen	
By:		
	Jim Olsen	
Name: _		
T:41	SVP and CPO	
Title:		
e-mail:	jim.olsen@atriumhea	ith.org
-		
Phone:	6 (2 = (2.2.4.2)	
	6/27/2019	
Date: _		

Da Vinci Xi

Define a new standard.



INTUÎTIVE





Define a new standard

Designed to provide flexibility for procedures performed across your robotics program, the da Vinci Xi® surgical system offers broader anatomical access, enhanced ease of use, and complete integration of the most advanced da Vinci® technology¹.

This fourth-generation system includes the same advanced 3DHD vision and wristed instruments you expect of da Vinci, in a modular, adaptable format.

With a surgical system this versatile, a new standard in minimally invasive care is possible.

Transform your approach

The da Vinci Xi® features boom-mounted arms with multi-position set up joints designed to help maximize the surgical workspace externally and internally. From a single cart location, staff has greater arm positioning capabilities¹, and surgeons can operate more easily across multiple quadrants¹ with the freedom to complete a wide range of minimally invasive procedures.



Pick your placement

Thinner arms and longer instruments enable simpler port placement from case to case.



Reach different angles

With Integrated Table Motion, you can reposition the patient without stopping the case to optimize access, exposure, and reach¹.



Get a different perspective

The small scope can be placed on any of the four arms during a procedure, giving you increased flexibility for visualizing the surgical site.¹

^{1.} Compared to the da Vinci Si surgical system. Results of testing on file.

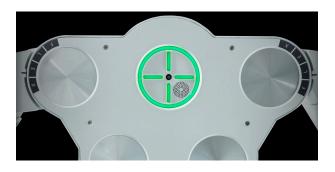
Operate with efficiency

Intuitive has spent thousands of hours over several decades working with surgical care teams to help streamline robotic-assisted surgery, which is why the da Vinci Xi® surgical system features help to get you started quickly and streamline essential tasks.



Start simply

A unique Guided Set Up has a user interface that is clear and easy to learn, with both visual and audible cues to facilitate quick boom deployment and precise setup.



Zero in on the right approach

Drive the patient-side cart toward the surgical table using the laser cross hairs to expedite connection to the ports.



Align the arms with little effort

Insert the endoscope so that the target anatomy is in view, then simply hold the targeting button as the remaining arms move into position automatically.



Put the power in your hands

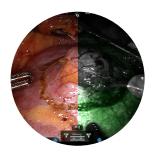
The integrated ERBE VIO dV generator helps you fine-tune energy output and switch presets directly from the surgeon console.

^{1.} Compared to the da Vinci Si surgical system. Results of testing on file.



Access the latest da Vinci innovations

Choosing the da Vinci Xi® surgical system means you can use the same instruments available for the da Vinci X®, enabling you to standardize instruments for your multi-port patient carts.



See tissue in a different light

Firefly* fluorescence imaging is built in to give you real-time visualization and assessment of vessels, bile ducts, and tissue perfusion.



Staple with control

Da Vinci Stapling offers a full range of lengths and reloads—30, 45, and 60 mm—as well as fully wristed articulation, complete surgeon control from the console, and software-driven feedback to help reduce guesswork.



Switch tasks quickly

With the ability to seal, cut, grasp, and dissect, Vessel Sealer Extend helps you flow seamlessly from one action to the next.



Get two grip strengths in one grasper

Force Bipolar with DualGrip technology can help streamline setup and minimize workflow disruptions by reducing instrument exchanges.

System comparison

	da Vinci X	da Vinci Xi	da Vinci SP
CORE TECHNOLOGY			
Da Vinci OS4 compatible			
Intuitive Motion	⊘	•	•
EndoWrist® Technology	⊘	⊘	✓
Immersive 3DHD Stereo Viewer	⊘	•	⊘
Upgradeable Architecture	✓	•	•
Single Port Platform	×	×	•
TECHNOLOGY ENHANCEMENTS ¹			
Dual Console Compatible			×
Single-Site® Technology	⊘	•	×
EndoWrist Stapler 45	<	•	×
Vessel Sealer Extend	<	•	×
Firefly® Fluorescence Imaging	<	•	×
Multi-Port Instruments & Endoscope	•	Ø	×
Integrated Energy	<	•	✓
Expanded Stapling Portfolio	•	Ø	×
Platform Modularity	•	•	⊘
EndoWrist Articulating Camera	×	×	<u> </u>
EnergyShield™ Monitoring	×	×	②
CAPABILITY ENHANCEMENTS ¹			
Streamlined Port Placement	⊘	•	•
Universal Single Port Placement	×	×	▽
Extended Anatomical Access	×	•	⊘
Integrated Table Motion	×	•	×
Boom Rotation	×	•	⊘
360° Axis Rotation	×	×	⊘
Single Port Distal Triangulation	×	×	•
EASE OF USE ENHANCEMENTS ¹			
Automated Setup Tasks	×		⊘
Advanced Intraoperative Adjustments	×	•	
Universal Cart Positioning	×	Ø	⊘
Optimized Patient Side Access	×	<u> </u>	<u> </u>
Elimination of Potential External Arm Collisions	×	×	Ø

¹Compared to the da Vinci Si® surgical system. Results of testing on file.

Purchasing information

Da Vinci Xi system

To contact a representative or receive additional information visit:

www.intuitive.com

or

call Intuitive Surgical Customer Service:

U.S.

1.877.408.3872

Europe

- +41.21.821.2020 or
- +800.0821.2020

Rest of the world

1.408.523.2100

What you get

The da Vinci X system has three main components as standard:

- 1. A unique **patient cart**
- 2. A **surgeon console** providing an immersive, ergonomic experience
- A vision cart supporting the latest
 3DHD vision system







Important safety information

Serious complications may occur in any surgery, including da Vinci® Surgery, up to and including death. Examples of serious or life-threatening complications, which may require prolonged and/or unexpected hospitalization and/or reoperation, include but are not limited to, one or more of the following: injury to tissues/organs, bleeding, infection and internal scarring that can cause long-lasting dysfunction/pain.

Risks specific to minimally invasive surgery, including da Vinci® surgery, include but are not limited to, one or more of the following: temporary pain/nerve injury associated with positioning; a longer operative time, the need to convert to an open approach, or the need for additional or larger incision sites. Converting the procedure could result in a longer operative time, a longer time under anesthesia, and could lead to increased complications. Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all da Vinci instruments.

For Important Safety Information, indications for use, risks, full cautions and warnings, please also refer to www.intuitive.com/safety.

Individuals' outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics and/or surgeon experience.

It is the responsibility of the owner of the da Vinci Surgical System to properly train and supervise its personnel to ensure that the instruments and accessories are properly cleaned, disinfected and sterilized as required by the User's Manual. The da Vinci products should not be used in a clinical setting unless the institution has verified that these products are properly processed in accordance with the da Vinci System User's Manual.

Firefly Fluorescence Imaging

The da Vinci® Fluorescence Imaging Vision System (Firefly® Fluorescence Imaging) is intended to provide

real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci Fluorescence Imaging Vision System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow, and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging. Fluorescence imaging of biliary ducts with the da Vinci Fluorescence Imaging Vision System is intended for adjunctive use only, in conjunction with standard of care white light and when indicated, with intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization. Intuitive's ICG packs are available for sale in the U.S. ONLY.

Intuitive's ICG packs are cleared for commercial distribution in the U.S. for use in combination with the fluorescence-capable da Vinci Xi HD vision system and Firefly integrated hardware. Intuitive-distributed ICG contains necessary directions for use of ICG with Firefly Fluorescence Imaging. Using generic ICG with Firefly Fluorescence Imaging is considered off-label and is not recommended. Anaphylactic deaths have been reported following ICG injection during cardiac catheterization. Total ICG dosage should not exceed 2 mg/kg per patient. Anaphylactic or urticarial reactions have been reported in patients with or without histories of allergy to iodides.

Vessel Sealer Extend

The EndoWrist® Vessel Sealer Extend is a bipolar electrosurgical instrument for use with a compatible da Vinci surgical system and the ERBE VIO® dV electrosurgical generator. It is intended for grasping and blunt dissection of tissue and for bipolar coagulation and mechanical transection of vessels up to 7mm in diameter and tissue bundles that fit in the jaws of the instrument. The EndoWrist Vessel Sealer Extend has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

Xi System Stapler Family

The EndoWrist® Stapler 30 and 45 Instruments and Reloads are intended to be used with the da Vinci Xi Surgical System (IS4000) for resection, transection, and/or creation of anastomoses in General, Thoracic, Gynecologic and Urologic surgery. The EndoWrist Staplers 30 and 45 are indicated for adult use, and the EndoWrist Stapler 30 is indicated for pediatric use. The devices can be used with staple-line or tissue-buttressing materials.

The EndoWrist Stapler 30 and 45 Instruments and Reloads should not be used on tissue such as the liver or spleen, where tissue compressibility is such that clamping of the instrument would be destructive. Do not use the EndoWrist Stapler 30 and 45 Instruments or Reloads on the aorta.

The EndoWrist Stapler 30 and 45 for the da Vinci Xi System (IS4000) are not compatible for use with the da Vinci, da Vinci S, or da Vinci Si Surgical Systems.

SureForm staplers

The Intuitive Surgical Stapler SureForm™ 60, Stapler SureForm 60 reloads, and other stapler accessories are intended to be used with a compatible da Vinci Surgical Systems for resection, transection, and, or creation of anastomoses in General, Thoracic, Gynecologic, Urologic, and Pediatric surgery. The device can be used with staple line or tissue buttressing material (natural or synthetic).

The Intuitive Surgical Stapler SureForm™ 45, Stapler SureForm 45 reloads, and other stapler accessories are intended to be used with a compatible da Vinci Surgical System for resection, transection, and, or creation of anastomoses in General, Thoracic, Gynecologic, Urologic, and Pediatric surgery. The device can be used with staple line or tissue buttressing material (natural or synthetic).

Force Bipolar

The Force Bipolar is intended to be used with compatible systems for endoscopic manipulation of tissue, including dissection, grasping, retraction, and bipolar coagulation of tissue.

Table Motion

Da Vinci Table Motion is intended to allow the surgical staff to reposition the patient by adjusting the table without undocking the da Vinci Xi® Surgical System during urologic surgical procedures, general laparoscopic surgical procedures, and gynecologic laparoscopic surgical procedures. It is designed to be used with a compatible OR table.

Unless otherwise noted, all people depicted are models.

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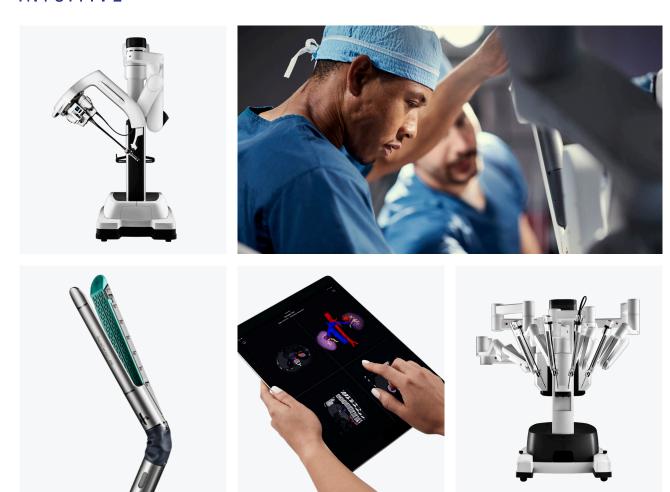
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PN1051540-US RevA 06/2019

References

Compared to the da Vinci Si® surgical system.
 Results of testing on file.

INTUÎTIVE



We believe minimally invasive care is lifeenhancing care. Through ingenuity and intelligent technology, we expand the potential of physicians to heal without constraints.





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From: Bass, Greg
To: Stancil, Tiffany C

Subject: [External] FW: AH Cabarrus Exemption Request for replacement da Vinci robot

Date: Wednesday, December 18, 2024 11:02:44 AM

Attachments: 2024 AH Cabarrus da Vinci Surgical Robot Replacement Exemption 12-17-24.pdf

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Hi Tiffany,

I forgot to copy you on this email. Please confirm receipt.

Thanks,

Greg Bass

Director

Core Market Growth Business Development

O: 704-355-0314 C: 704-906-3771

Atrium Health

From: Bass, Greg

Sent: Tuesday, December 17, 2024 2:47 PM

To: 'greg.yakaboski@dhhs.nc.gov' <greg.yakaboski@dhhs.nc.gov>

Subject: AH Cabarrus Exemption Request for replacement da Vinci robot

Hi Greg,

I have attached an exemption request from AH Cabarrus to replace a dual console da Vinci robot. I will send the product brochure in a separate email due to the large file size.

Please let me know if you have any questions or need anything else.

Greg Bass

Director

Core Market Growth Business Development

O: 704-355-0314 C: 704-906-3771

Atrium Health

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