



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

October 26, 2017

Lynn DeJaco
155 Memorial Drive
Pinehurst, NC 28374

No Review

Record #: 2426
Facility Name: FirstHealth Moore Regional Hospital
FID #: 943358
Business Name: FirstHealth of the Carolinas
Business #: 2724
Project Description: Acquire a second daVinci robotic surgical system
County: Moore

Dear Ms. DeJaco:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter on October 24, 2017 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 your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that 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.

However, you 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.

It should be noted that this determination is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION
WWW.NCDHHS.GOV

TELEPHONE 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603

MAILING ADDRESS: 2704 MAIL SERVICE CENTER • RALEIGH, NC 27699-2704

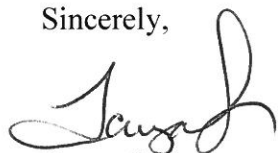
AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER



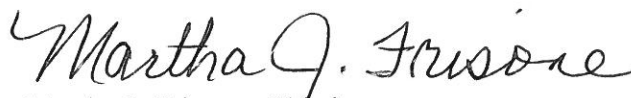
original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility ID # (FID) if the facility is licensed.

Sincerely,



Tanya S. Rupp
Project Analyst



Martha J. Frisone, Chief
Healthcare Planning and Certificate of Need Section

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR

May 25, 2017

Ms. Martha Frisone
Assistant Chief, Healthcare Planning and Certificate of Need Section
Department of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603



RE: Request for No Review Determination to Acquire daVinci Robotic Surgical System /
Moore County
FID 943358 NR id 2426
Bw id 2724

Dear Ms. Frisone:

FirstHealth Moore Regional Hospital intends to acquire and operate a second daVinci robotic surgical system from Intuitive Surgical, Inc and requests a determination that the project falls within the definition of NCGS 131E-176(16)(b), as exempt from review.

Exemption from Review

NCGS 131E-176(14o) defines a "major medical equipment" as a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars (\$750,000). In determining whether the major medical equipment does costs more than seven hundred fifty thousand dollars (\$750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital equipment 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 as defined in this section.

NCGS 131E-176(16)(b) defines "new institutional health service" as the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall included in determining if the expenditure exceeds two million dollars (\$2,000,000).

Compliance

1. The estimated cost for the acquisition of the daVinci robotic surgical system and all related equipment is \$735,000. Please refer to Exhibit A for the vendor quote.
2. There are no renovation or room up-fit costs associated with this project.
3. Total project costs including costs of the daVinci robotic surgical system, other equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the daVinci robotic surgical system at FMRH is \$735,000. Please refer to Exhibit B for the project's capital cost.

Determination Requested

FirstHealth Moore Regional Hospital requests that the Division of Health Service Regulation make a determination that the acquisition of the daVinci robotic surgical system, as proposed herein does not constitute a new institutional health service or major medical equipment and is thus exempt from certificate of need review.

If you require additional information concerning this request, please contact me at 910-715-1000.

Sincerely,



Lynn DeJaco
Senior Vice President and CFO

Attachments: Exhibit A - Equipment Quote
 Exhibit B - Proposed Total Capital Cost of Project

INTUITIVE SURGICAL

Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086
800-876-1310

Taking surgical precision beyond the limits of the human hand

Quote Details		Company Information	
Quote ID	83184.0	Hospital Name	FirstHealth Moore Regional Hospital
Quote Date	5/24/2017	NS ID / IDN Affiliation	13737/MedCath Corporation
Valid Until	6/15/2017	Address	155 Memorial Dr
Sales Rep	Todd Headrick	City, State, Zip	Pinehurst, NC, 28374
Phone Number	1(843) 991-4849	Contact Name	
Email	Todd.Headrick@intusurg.com	Telephone	

Please Fax all Purchase Orders to: 408-523-2377

Items

Part Number	Qty	Item	Price	Subtotal
da Vinci Systems				
	1	da Vinci® Xi® System One (1): da Vinci® Xi™ System Surgeon Console One (1): da Vinci® Xi™ System Patient Cart One (1): da Vinci® Xi™ System Vision Cart da Vinci® Xi™ System Documentation including: User's Manual For System User's Manual for Instruments and Accessories One (1) da Vinci® Xi™ Cleaning & Sterilization Kit Two (2) da Vinci® Xi™ Instrument Release Kit (IRK) da Vinci® Xi™ System Software 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): 8 mm Instrument Introducer One (1): Box of 10: Tip Cover for Hot Shears™ (MCS) One (1): Pmed Cable, Covidien Force Triad ESU Drapes Two (2): Pack of 20 da Vinci® Xi™ Arm Drape One (1): Pack of 20 da Vinci® Xi™ Column Drape 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 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 (all kits subject to change without notice)	\$725,000.00	\$725,000.00
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)	\$10,000.00	\$10,000.00
Total				\$735,000.00

Leasing Terms

Leasing options are available through Intuitive Surgical or another designated financier 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 Reprocessing Instructions Part #557085. 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. Pricing is subject to applicable shipping costs and taxes. Pricing is subject to change without notice. A \$9.95 handling charge will be applied for any shipments using a customer designated carrier.

4) Return Goods Policy :

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

5) Exchange Goods Policy :

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

6) Credit Policy :

6.1 Intuitive Surgical will issue credit against original purchase order after full inspection is complete. Credit for defective returns: Intuitive Surgical will issue credit on products based on failure analysis performed and individual warranty terms. For instruments, credit will be issued for the remaining lives, plus one additional life to compensate for usage at the time the issue was identified. Evidence of negligence, misuse and mishandling will not qualify for credit. Credit for excess inventory returns: Excess Inventory returns will be valued at the invoice price less a 15% restocking fee. 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 B

PROPOSED CAPITAL COSTS

Project name: daVinci Robotic Surgical System

Proponent: FirstHealth Moore Regional Hospital

Site Costs		
(1)	Full purchase price of land _____ Acres at \$_____ per acre	N/A
(2)	Closing costs	N/A
(3)	Site inspection and survey	N/A
(4)	Legal fees/subsoil investigation	N/A
(5)	Site preparation costs	N/A
(6)	Other (Demolition)	N/A
(7)	Sub-Total Site Costs	N/A
Construction Contract		
(8)	Cost of materials	N/A
(9)	Other (Specify)	N/A
(10)	Sub-Total Construction Contract	N/A
Miscellaneous Project Costs		
(11)	Building purchase	N/A
(12)	Fixed equipment purchase/lease	N/A
(13)	Movable equipment purchase/lease	\$735,000
(14)	Furniture	N/A
(15)	Landscaping	N/A
(16)	Consultant fees	N/A
(17)	Financing costs (e.g. bond, loan, etc.)	N/A
(18)	Interest during construction	N/A
(19)	Other (Contingency)	N/A
(20)	Sub-Total Miscellaneous	\$735,000
(21)	TOTAL CAPITAL COST OF PROJECT	\$735,000

I assure that, to the best of my knowledge, the above capital costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.



 Lynn DeJaco, Senior Vice President and CFO

5/31/17

 Date