



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

March 16, 2020

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

No Review

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

Dear Ms. Runyon:

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

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

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

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

Sincerely,
Michael J. McKillip
Project Analyst

Martha J. Frisone
Martha J. Frisone
Chief

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

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

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



March 5, 2020

VIA ELECTRONIC MAIL

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

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

Dear Mr. McKillip:

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

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

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

Sincerely,

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

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



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

Part Number	Qty	Item	Price	Discount	Subtotal
da Vinci Systems					
	1	da Vinci Xi® Single Console System One (1): da Vinci Xi System Surgeon Console One (1): da Vinci Xi System Patient Cart One (1): da Vinci Xi System Vision Cart da Vinci Xi System Documentation da Vinci Xi System Software Training Instrument Starter Kit Accessory Starter Kit Drapes Vision Equipment (All Kits subject to change without notice)	\$1,900,000.00	\$1,175,000.00	\$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	\$0.00	\$10,000.00
Total					\$735,000.00
Service					
Part Number	Qty	Item	Price	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@unhealth.unc.edu>
Sent: Thursday, March 5, 2020 9:48 AM
To: Mckillip, Mike
Cc: 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@unhealth.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.