



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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

VIA EMAIL ONLY

May 13, 2021

Danny Waller
Danny.waller@onslow.org

Exempt from Review – Replacement Equipment

Record #: 3557
Date of Request: May 7, 2021
Facility Name: Onslow Memorial Hospital, Inc.
FID #: 923383
Business Name: Onslow Memorial Hospital, Inc.
Business #: 1354
Project Description: Replace da Vinci robotic system
County: Onslow

Dear Mr. Waller:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Intuitive da Vinci Robotic System, Model Xi to replace the Intuitive da Vinci Robotic System, Model Si, Serial #258213. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Gregory F. Yakaboski
Project Analyst

for
Lisa Pittman
Acting Chief, Certificate of Need

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



May 4, 2021

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

**RE: Request for No Review Determination / Acquisition of da Vinci Xi Surgical System /
Onslow Memorial Hospital / Onslow County**

Dear Ms. Frisone:

Onslow Memorial Hospital, Inc. ("OMH") 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 which OMH 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 OMH must incur to acquire the equipment and make it operational.

OMH 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 910-577-2830 or danny.waller@onslow.org

Sincerely,

Daniel T. Waller
Senior Vice President of Support Services
Onslow Memorial Hospital

EXHIBIT 1.

08 Apr 2021 - 10:02:28 (-07:00)



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

| Quote Details | | Company Information | |
|---------------|-------------------------|-------------------------|--------------------------------|
| Quote ID | 151559.0 | Hospital Name | Onslow Memorial Hospital |
| Quote Date | 4/8/2021 | SF ID / IDN Affiliation | 13786/Onslow Memorial Hospital |
| Valid Until | 6/30/2021 | Address | 317 Western Blvd |
| Sales Rep | Hank Warren | City, State, Zip | Jacksonville, NC, 28541 |
| Phone Number | 1(919) 602-7841 | Contact Name | |
| Email | Hank.Warren@mbc.org.com | Telephone | |

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

| Items | | | | |
|---------------------------------|-----|--|----------------|---------------------|
| Part Number | Qty | Item | Price | Subtotal |
| da Vinci Systems | | | | |
| | 1 | 453000 DA VINCI SI TRADE-IN SYSTEM | \$0.00 | \$0.00 |
| | 1 | da Vinci X08 Single Console System One (1): da Vinci X8 System Surgeon Console One (1): da Vinci X8 System Patient Cart One (1): da Vinci X8 System Vision Cart da Vinci X8 System Documentation da Vinci X8 System Software Training Instrument Starter Kit Accessory Starter Kit Drapes Vision Equipment (AS file subject to change without notice) | \$1,900,000.00 | \$1,175,000.00 |
| da Vinci System Upgrades | | | | |
| | 1 | E-100 generator is a bipolar electrocautery unit (ESU) used with compatible EV instruments - SynchroSeal and VEE | \$25,000.00 | \$25,000.00 |
| | 1 | da Vinci X08 Integrated Table Motion Sold with System Upgrade Includes: - Table Connection hardware module for patient cart - Integrated Table Motion software Upgrade Note: Integrated Table Motion requires connection to a Trumpf Medical TruSystem 7000dV operating table for feature use. The TruSystem 7000dV operating table is sold and serviced by Trumpf Medical. | \$75,000.00 | \$75,000.00 |
| Freight | | | | |
| | 1 | System Freight - East (AL, CT, DC, DE, FL, GA, IL, IN, KY, MA, MD, ME, MI, MN, NC, NH, NJ, NY, OH, PA, RI, TN, SC, VA, VT, WV) | \$12,000.00 | \$12,000.00 |
| Total | | | | \$725,000.00 |
| Service | | | | |
| Part Number | Qty | Item | Price | Subtotal |
| | 1 | Da Vinci X08 dV Complete Care Service Plan (single console) Years 2-5, per year | \$299,200.00 | \$299,200.00 |
| | 1 | Year One System Service (Included in System Fee unless an amount is listed) | \$299,200.00 | \$299,200.00 |

| Equipment to be Returned | |
|--|---|
| da Vinci System | SH0899 - Single HD Console System and Vessel Sealer Generator |
| da Vinci 0 Degree Endoscopes Quantity | 3 |
| da Vinci 30 Degree Endoscopes Quantity | 4 |
| da Vinci Camera Heads Quantity | 1 |

| Additional Information | |
|---|--|
| * \$50k IFA Credit | |
| * There is a trade value of 150k built into the service and reflected as a line itemed capital trade value of \$0 | |

| 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

| |
|---|
| <p>1) System Terms and Conditions:</p> <p>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</p> |
|---|

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. 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. 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

From: [Danny Waller](#)
To: [Yakaboski, Greg](#)
Cc: [Penney Burlingame](#); [Carl Biber](#); [Maire Corcoran Ragozzine \(maire.ragozzine@unhealth.unc.edu\)](#)
Subject: [External] Additional Information to May 4th Request for No Review Determination
Date: Wednesday, May 12, 2021 2:53:25 PM

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

This message was sent securely using ZixCorp.

Dear Mr Yakaboski,

This email is to provide additional clarification to the May 4, 2021 Request for No Review Determination da Vinci X1 Surgical System. We recognize our letter should have requested and “Exemption”, and apologize for any confusion.

Equipment

| | |
|---|---|
| Old - Intuitive da Vinci Robot System | Model Si, Serial # 258213 |
| New – Intuitive da Vinci Robotic System | Model Xi, Serial # “unknown at this time” |

Onslow Memorial Hospital will insure that the existing unit will not be sold or otherwise disposed of and will not be used again the State without first obtaining a certificate of need if one is required. We will be happy to assist with any additional information necessary for your determination of this request.

Sincerely,

Daniel T. Waller

Sr VP of Support Services

Onslow Memorial Hospital

This message was secured by [ZixCorp](#)^(R).