



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

Dorsey Tobias
Dorsey.tobias@unchealth.unc.edu

Exempt from Review – Replacement Equipment

Record #:

Date of Request: April 30, 2021
Facility Name: Nash General Hospital
FID #: 933368
Business Name: Nash Health Care Systems
Business #: 1288
Project Description: Replace da Vinci robotic system
County: Nash

Dear Ms. Tobias:

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 2021 Intuitive Surgical da Vinci Xi surgical system to replace the 2012 Intuitive Surgical da Vinci Si surgical system serial #SH1260. 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
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



2460 Curtis Ellis Drive, Rocky Mount, NC 27804
252 962-8000 / www.nashu3nhealthcare.org

April 30, 2021

Via E-MAIL

Greg Yakaboski, Project Analyst, Certificate of Need
N.C. Department of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

RE: Nash UNC Health Care
Replacement of Da Vinci Robotic System
Seeking CON Exemption NCGS 131E-184(a)(7)
Rocky Mount, NC (FID 933368; Nash County)

Dear Mr. Yakaboski,

Nash Health Care Systems (d.b.a. "Nash UNC Health Care", "Nash UNC") seeks to replace an existing Da Vinci Si robotic system with a new Da Vinci Xi robotic system from Intuitive Surgical, and locate it at Nash UNC's Surgical Department located at 2460 Curtis Ellis Drive, Rocky Mount, NC 27804, which is part of Nash UNC's main campus. The existing robot will be decommissioned and 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.

The purpose of this letter is to provide the Agency with notice and to request a determination that the purchase of the replacement Da Vinci robotic system is exempt from Certificate of Need ("CON") review because it is consistent with the replacement equipment definition outlined in N.C. Gen. Stat. 131E-176(22a) which states that the replacement equipment is comparable to the equipment being replaced if it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements. Additionally, the project costs less than two million dollars 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.

Pursuant to 10A N.C.A.C.14C.0303 the proposed Da Vinci robot meets the replacement equipment definition because:

1. It is comparable to the equipment currently in use. It has the same technology as the equipment currently in use, although it does possess expanded capabilities due to technological improvements.
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.
3. The acquisition of the proposed Da Vinci robot will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.
4. The existing equipment was not purchased second-hand nor was the existing equipment leased.
5. The replacement equipment is not capable of performing procedures that will result in the provision of a new health service or type of procedure that has not been provided with the existing equipment.

The costs related to the replacement totals \$725,000. Included in the total is: \$725,000, the new equipment cost, per Attachment A – Vendor Equipment Quote.

In support of our request, please find attached:

- Attachment A – Vendor Equipment Quote
- Attachment B – Equipment Comparison Chart

Nash UNC hereby requests that the Agency provide a written response confirming that the purchase of a replacement Da Vinci robot for the hospital space described herein does not require CON review. If the Agency needs additional information to assist in its consideration of this request, please apprise us as soon as possible. We thank you for your consideration of this request.

Sincerely,

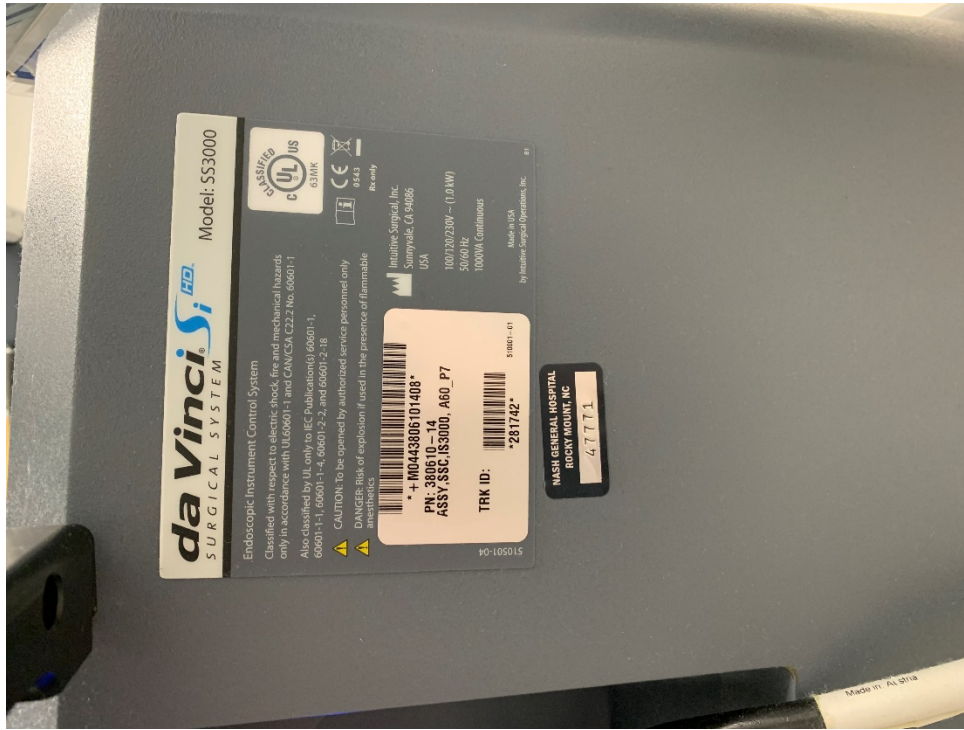
Dorsey Tobias
Executive Director, Marketing, Communications & Strategy
Nash UNC Health Care

Enclosures

Nash General Hospital, Nash Day Hospital, Coastal Plain Hospital, and Bryant T. Aldridge Rehabilitation Center

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	Surgical Robot	Surgical Robot
Manufacturer	Intuitive Surgical	Intuitive Surgical
Model number	Da Vinci Si	Da Vinci Xi
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	Model: Da Vinci Si Serial #: SH1260	Pending Approval
Is the equipment mobile or fixed?	NA	NA
Date of acquisition	2012	2021
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	Unavailable	\$725,000
Total cost of the equipment	Unavailable	\$725,000
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	Nash UNC Hospital	Nash UNC Hospital
Document that the existing equipment is currently in use	Attached	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 <Attach a separate sheet if necessary>	<ul style="list-style-type: none"> - Urology: Prostatectomy, Partial Nephrectomy, Pyeloplasty, Cystectomy - Gynecology: Benign Hysterectomy, Salpingo Oophorectomy, Myomectomy - General Surgery: Cholecystectomy, Inguinal Hernia, Ventral Hernia, Hiatal Hernia, Colon Resection, Sleeve Gastrectomy 	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	Same as Existing



From: [Yakaboski, Greg](#)
To: [Waller, Martha K](#)
Subject: FW: [External] Nash UNC Health Care Seeking CON Exemption NCGS 131E-184(a)(7) - Replacement of Existing Da Vinci Robotic System
Date: Friday, April 30, 2021 12:07:18 PM
Attachments: [image001.png](#)
[Surgical Robot Replacement - Nash UNC Letter Requesting Exemption.docx](#)
[Surgical Robot Replacement - Nash Da Vinci Equipment Comparison Chart.docx](#)
[Surgical Robot Replacement - proof of use of existing equipment.docx](#)

Just received this exemption request.

Sincerely,

Gregory F. Yakaboski

Gregory F. Yakaboski
Project Analyst
[Division of Health Service Regulation](#), Certificate of Need
[NC Department of Health and Human Services](#)

Help protect your family and neighbors from COVID-19.
[Know the 3 Ws. Wear. Wait. Wash.](#)
#StayStrongNC and get the latest at nc.gov/covid19

Office: 919-855-3873
Greg.Yakaboski@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704

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From: Tobias, Dorsey <Dorsey.Tobias@unchealth.unc.edu>
Sent: Friday, April 30, 2021 11:30 AM
To: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>
Subject: [External] Nash UNC Health Care Seeking CON Exemption NCGS 131E-184(a)(7) - Replacement of Existing Da Vinci Robotic System

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Dorsey Tobias
Executive Director, Marketing, Communications & Strategy

Nash UNC Health Care

Enclosures

Dorsey Tobias | Executive Director
Marketing, Communications & Strategy
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