



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

August 31, 2021

Kristy Hubard
Kristy.hubard@nhrmc.org

Exempt from Review – Replacement Equipment

Record #: 3671
Date of Request: August 20, 2021
Facility Name: Novant Health New Hanover Regional Medical Center
FID #: 943372
Business Name: Novant Health New Hanover Regional Medical Center, LLC
Business #: 3330
Project Description: Replace two existing Intuitive Si HD daVinci surgical systems
County: New Hanover

Dear Ms. Hubard:

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 two Intuitive daVinci Si HD Surgical Systems to replace two existing Intuitive daVinci Si HD Surgical Systems. This determination is based on your representations that the existing units 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,

[Handwritten signature of Tanya M. Saporito]

Tanya M. Saporito
Project Analyst

[Handwritten signature of Micheala Mitchell]

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section
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

August 20, 2021

Ms. Micheala Mitchell, Chief  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
NC Department of Health and Human Services  
2704 Mail Service Center  
Raleigh, North Carolina 27699-2704

RE: Request for No Review Determination for Replacement of Equipment / New Hanover County  
FID # 943372

Dear Ms. Mitchell:

Pursuant to 10A NCAC 14C.0202, Novant Health New Hanover Regional Medical Center ("NHNHRMC") intends to replace two Intuitive daVinci Si HD Surgical Systems and requests a determination that such replacement is exempt from review because it falls within the definition of NCGS § 131E-184 (a)(7) and the regulations set out in 10A NCAC 14C.0303. The existing Intuitive daVinci Si HD Surgical Systems at NHRMC 17<sup>th</sup> Street were installed in 2013, however systems that allow for colorectal and thoracic robotic procedures are now available. There are no construction or renovation costs associated with this project.

#### **daVinci Surgical System Replacement**

Site	Equipment to be Replaced	Trade-in of Existing	Total Project Cost
NHNHRMC 17 <sup>th</sup> Street	Intuitive daVinci Si HD Surgical System	Yes	\$725,000
NHNHRMC 17 <sup>th</sup> Street	Intuitive daVinci Si HD Surgical System	Yes	\$725,000

#### **Exemption from Review**

Pursuant to NCGS § 131E-184(a): "The department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, when notice includes an explanation of why the new institutional health service is required, for any of the following: ... (7) To provide replacement equipment."

NCGS § 131E-176(22a) defines "replacement equipment" as equipment that costs less than \$2,000,000 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.

#### **Applicable Regulations**

10A NCAC 14C.0303 defines "not comparable" replacement equipment if:

- 1) the replacement equipment to be acquired is capable of providing a health service that the equipment to be replaced cannot provide; or

- 2) the equipment to be replaced was acquired less than 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section and it was refurbished or reconditioned when it was acquired by the person requesting the exemption.

### **Compliance**

NHNHRMC hereby certifies that:

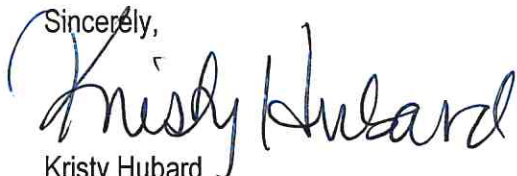
1. The estimated individual project costs for the replacement of the two existing Intuitive daVinci Si HD Surgical Systems is less than \$2,000,000 each.
2. The replacement equipment will be purchased for the sole purpose of replacing equipment currently in use that will be traded in for disposal and removed from North Carolina. A comparison of the existing and replacement equipment is provided in Exhibit A.
3. The existing equipment was not purchased refurbished or reconditioned when NHNHRMC acquired the equipment in January 2013.

### **Determination Requested**

NHNHRMC requests that the Healthcare Planning and Certificate of Need Section makes a determination that the replacement of the Intuitive daVinci Si HD Surgical Systems, as proposed herein, does not constitute new institutional health services and is thus exempt from certificate of need review.

If you have any questions or need additional information, please do not hesitate to contact me at (910) 667-5908.

Sincerely,



Kristy Hubard  
Chief Strategy Officer  
Novant Health New Hanover Regional Medical Center

Exhibit A - Equipment Comparison

**EQUIPMENT COMPARISON**

Exhibit A

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Surgery Robot	Surgery Robot
Manufacturer of Equipment	Intuitive Surgical	Intuitive Surgical
Tesla Rating for MRIs		
Model Number	da Vinci Si HD	da Vinci Xi
Serial Number (Magnet Serial #)	1599	TBD
Provider's Method of Identifying Equipment (Version)	Facility Asset Tag / Serial #	Facility Asset Tag / Serial #
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	1/31/2013	TBD
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.)	\$735,000	\$725,000
Total Cost of Equipment	\$735,000	\$725,000
Fair Market Value of Equipment	\$100,000	N/A
Net Purchase Price of Equipment	\$735,000	\$725,000
Locations Where Operated	17 <sup>th</sup> St Main Operating Room	17 <sup>th</sup> St Main Operating Room
Number Days In Use/To Be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	N/A	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	N/A	0%
Type of Procedures Currently Performed on Existing Equipment	Robotic General, Gynecological, and Urological procedures	Robotic General, Gynecological, and Urological procedures
Type of Procedures New Equipment is Capable of Performing	N/A	Colorectal & Thoracic Robotic Procedures

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Surgery Robot	Surgery Robot
Manufacturer of Equipment	Intuitive Surgical	Intuitive Surgical
Tesla Rating for MRIs		
Model Number	da Vinci Si HD	da Vinci Xi
Serial Number (Magnet Serial #)	1600	TBD
Provider's Method of Identifying Equipment (Version)	Facility Asset Tag / Serial #	Facility Asset Tag / Serial #
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	1/31/2013	TBD
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
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Type of Procedures New Equipment is Capable of Performing	N/A	Colorectal & Thoracic Robotic Procedures