



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

CORRECTION

January 22, 2019

Marisa Barone
Wake Forest Baptist Health
Medical Center Boulevard
Winston-Salem, NC 27157

Exempt from Review – Replacement Equipment

Record #: 2833
Facility Name: High Point Regional Health
FID #: 943251
Business Name: Wake Forest Baptist Health
Business #: 2990
Project Description: Replace da Vinci Si robot
County: Guilford

Dear Ms. Barone:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of January 4, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Intuitive Surgical Xi da Vinci robot to replace the Intuitive Surgical Si da Vinci robot. 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.

Moreover, you need to contact the Agency's Construction, and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

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,

Gloria C. Hale
Team Leader

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

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Melinda Boyette, Administrative Assistant, Healthcare Planning, 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: 2704 Mail Service Center, Raleigh, NC 27699-2704
www.ncdhhs.gov/dhsr • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Hale, Gloria

From: Marisa A. Barone <mbarone@wakehealth.edu>
Sent: Tuesday, January 08, 2019 11:57 AM
To: Hale, Gloria
Subject: [External] RE: Add'l follow up question re. exemption request

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Hi Gloria, yes the robot that is being replaced will be disposed of by the vendor / manufacturer. It will not be used again in North Carolina without first obtaining a CON, if one is required.

Thanks,
Marisa

Marisa Barone
336.713.0697

From: Hale, Gloria <gloria.hale@dhhs.nc.gov>
Sent: Tuesday, January 08, 2019 11:55 AM
To: Marisa A. Barone <mbarone@wakehealth.edu>
Subject: Add'l follow up question re. exemption request

Marisa, will the da Vinci robot to be replaced be sold or otherwise disposed of and not be used again in the State without first obtaining a certificate of need if one is required?

Gloria C. Hale, MPH

Team Leader, Certificate of Need

[Division of Health Service Regulation \[ncdhhs.gov\]](#), Healthcare Planning and Certificate of Need Section
[NC Department of Health and Human Services \[ncdhhs.gov\]](#)

Office: 919-855-3873
Gloria.Hale@dhhs.nc.gov

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

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From: Marisa A. Barone [<mailto:mbarone@wakehealth.edu>]
Sent: Tuesday, January 08, 2019 11:20 AM
To: Hale, Gloria <gloria.hale@dhhs.nc.gov>
Subject: [External] RE: Exemption request da Vinci

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Hi Gloria, please see below for responses to your questions. Please let me know if there is any additional information that is needed.

- Unit Being Replaced:
 - Manufacturer = Intuitive Surgical
 - Model = da Vinci "Si"
- New Units (both the replacement and the new unit will be the manufacturer and model):
 - Manufacturer = Intuitive Surgical
 - Model = da Vinci "Xi"
- There will not be any additional installation, construction, training or other costs associated with making the incremental da Vinci XI Robot operational that is not already included in the \$725,000.

Thanks,
Marisa

Marisa Barone
336.713.0697

From: Hale, Gloria <gloria.hale@dhhs.nc.gov>
Sent: Monday, January 07, 2019 3:26 PM
To: Marisa A. Barone <mbarone@wakehealth.edu>
Subject: Exemption request da Vinci

Hi Marisa. We are in receipt of your request for an exemption from CON law for the replacement of a da Vinci robot and for the purchase of an incremental da Vinci XI Robot.

Could we please get the manufacturer and model # for the unit that is being replaced and also the same info for the intended new unit?

In addition, will there be any installation, construction, training or other costs associated with making the incremental da Vinci XI Robot operational? If you have an intended make and model for that unit, that would be helpful as well.
Thanks.

Gloria C. Hale, MPH

Team Leader, Certificate of Need

[Division of Health Service Regulation \[ncdhhs.gov\]](http://ncdhhs.gov), Healthcare Planning and Certificate of Need Section
[NC Department of Health and Human Services \[ncdhhs.gov\]](http://ncdhhs.gov)

Office: 919-855-3873
Gloria.Hale@dhhs.nc.gov

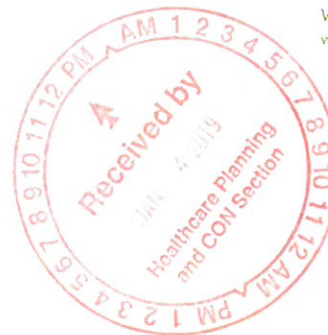
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January 4, 2019

Ms. Martha Frisone, Chief
Ms. Celia Inman, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603



**Re: Request for Confirmation of Exemption for High Point Regional Health (FID # 943251; Lic # H0052)
Replacement of Existing da Vinci Si Robot and Purchase of Incremental da Vinci Xi Robot**

Dear Ms. Frisone and Ms. Inman,

I am writing to request confirmation that the project described below for High Point Regional Health ("HPRH") does not require CON review.

HPRH plans to replace the existing da Vinci Si robot with a 2019 da Vinci Xi robot from Intuitive Surgical. The Si is an older platform from Intuitive Surgical that is being phased out in favor of the Xi. The Xi has four arms and can rotate and pivot in any direction. The arms can be disconnected and reconnected mid-procedure, if needed. The total capital cost of the project including equipment, installation, and related construction expenditures totals \$725,000.

In addition to the replacement robot, HPRH plans to purchase an incremental Xi robot. The estimated capital cost of the incremental Xi robot, including equipment, installation, and related construction expenditures totals \$725,000.

The projected cost of both the incremental and replacement da Vinci Xi robots, including equipment, installation, and related construction expenditures totals \$725,000 per robot. As such, the cost is below the threshold for major medical equipment as defined in NC G.S. § 131E-176 (14o) and acquisition of the equipment is not considered a new institutional health service pursuant to NC G.S. § 131E-176 (16).

HPRH respectfully requests confirmation from the CON Section that the replacement of the existing Si da Vinci robot and purchase of the incremental Xi da Vinci robot are exempt from CON review.

Please let me know if you have any questions or if additional information is needed.

Sincerely,

A handwritten signature in blue ink that reads "Marisa Barone".

Marisa Barone
Director, Strategic Planning and Regulatory / CON
Wake Forest Baptist Health