



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

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

January 10, 2019

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

**No Review**

**Record #:** 2834  
**Facility Name:** High Point Regional Health  
**FID #:** 943251  
**Business Name:** Wake Forest Baptist Health  
**Business #:** 2990  
**Project Description:** Acquire incremental da Vinci Xi robot  
**County:** Guilford

Dear Ms. Barone:

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 Construction, and Acute and Home Care Licensure and Certification Sections 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.

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/](http://www.ncdhhs.gov/dhsr/) • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Sincerely,



Gloria C. Hale  
Team Leader

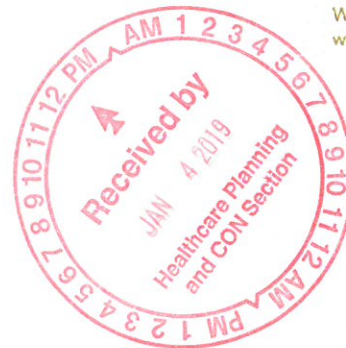


Martha J. Frisone, Chief  
Healthcare Planning and Certificate of Need Section

cc: Construction Section, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR  
Melinda Boyette, Administrative Assistant, Healthcare Planning, DHSR

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



## Hale, Gloria

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**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](mailto:Gloria.Hale@dhhs.nc.gov)

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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](mailto: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

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**From:** Hale, Gloria <[gloria.hale@dhhs.nc.gov](mailto:gloria.hale@dhhs.nc.gov)>  
**Sent:** Monday, January 07, 2019 3:26 PM  
**To:** Marisa A. Barone <[mbarone@wakehealth.edu](mailto: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://www.ncdhhs.gov), Healthcare Planning and Certificate of Need Section  
[NC Department of Health and Human Services \[ncdhhs.gov\]](http://www.ncdhhs.gov)

Office: 919-855-3873  
[Gloria.Hale@dhhs.nc.gov](mailto:Gloria.Hale@dhhs.nc.gov)

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