



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

November 5, 2020

Anna Post Mickleberry
apost@wakehealth.edu

Exempt from Review – Replacement Equipment

Record #: 3406
Facility Name: North Carolina Baptist Hospital
FID #: 943495
Business Name: North Carolina Baptist Hospital
Business #: 1819
Project Description: Replace existing Medtronic Mazor-Renaissance Robotic Guidance System
County: Forsyth

Dear Ms. Mickleberry:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of November 3, 2020, 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 Medtronic Mazor-X Robotic Guidance System to replace the Medtronic Mazor-Renaissance Robotic Guidance System, Serial #300-114-112015. 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 Radiation Protection Section 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,

Celia C. Inman
Celia C. Inman
Project Analyst

Martha J. Frisone
Martha J. Frisone
Chief

cc: Radiation Protection 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

November 3, 2020

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 North Carolina Baptist Hospital (FID # 943495; Lic # H0011), Replacement Mazor Robotic Guidance System Equipment**

Dear Ms. Inman,

Pursuant to NC G.S. § 131E-184 (a.7), Exemptions from Review, I am writing to request confirmation that the project described below for North Carolina Baptist Hospital (NCBH) is exempt from review.

North Carolina Baptist Hospital (“NCBH”) plans to replace the existing Mazor Renaissance System with the Medtronic Mazor X Robotic Guidance System. The new Mazor Robotic Guidance System provides robotic guidance along with pre and post-operative planning for spine surgery. The Mazor Renaissance Robotic System was purchased in March of 2016 but has already become obsolete. The existing unit will be traded in. The total capital cost of the project is \$682,166. The existing Renaissance System will be removed and disposed of by the equipment vendor.

NCBH respectfully requests that the facts stated above, as well as the information included in the Attachments, serve as prior written notification to the Department that the replacement of the Mazor Renaissance System at NCBH meets all of the exemption criteria in NC G.S. § 131E-184 (a.7).

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

Sincerely,

*Anna Post Mickleberry*

Anna Mickleberry  
Director, Network Strategy and Business Development

## EQUIPMENT COMPARISON

|  | <b>EXISTING<br/>EQUIPMENT</b>       | <b>REPLACEMENT<br/>EQUIPMENT</b>    |
|--|-------------------------------------|-------------------------------------|
| Type<br>(e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment) | Other Major<br>Medical<br>Equipment | Other Major<br>Medical<br>Equipment |
| Manufacturer   | Medtronic                           | Medtronic                           |
| Model number   | Mazor -<br>Renaissance              | Mazor - X                           |
| Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)   | Mazor – Serial #<br>300-114-112015  | Mazor- Item #<br>MAZORXRGUS         |
| Is the equipment mobile or fixed?  | Mobile                              | Mobile                              |
| Date of acquisition  | 3/2016                              | 11/2020                             |
| 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 <Attach a signed Projected Capital Cost form>  | NA                                  | \$682,166                           |
| Total cost of the equipment  | \$500,000                           | \$682,166                           |
| Location of the equipment <Attach a separate sheet for mobile equipment if necessary>  | Winston ORs only                    | Winston ORs only                    |
| Document that the existing equipment is currently in use   | Currently in Use                    | NA                                  |
| Will the replacement equipment result in any increase in the <b>average charge per procedure</b> ?   | NA                                  | No                                  |
| If so, provide the increase as a percent of the current average charge per procedure   | NA                                  | N/A                                 |
| Will the replacement equipment result in any increase in the <b>average operating expense per procedure</b> ?  | 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>  | Spine surgery                       | NA                                  |
| Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>   | NA                                  | Spine surgery                       |

Date of last revision: 5/17/19

**From:** [Inman, Celia C](#)  
**To:** [Waller, Martha K](#)  
**Subject:** FW: [External] Update - NCBH Request for Confirmation on CON Exemption  
**Date:** Thursday, November 5, 2020 8:29:40 AM  
**Attachments:** [image001.png](#)  
[Replacement Equipment Comparison Form - Stealth Station.pdf](#)  
[2020 NCBH Stealth Station replacement equipment letter.pdf](#)  
[2020 NCBH Mazor replacement equipment letter.pdf](#)  
[2020 NCBH O-arm replacement equipment letter.pdf](#)  
[Replacement Equipment Comparison Form - O Arm.pdf](#)  
[Replacement Equipment Comparison Form - Mazor .pdf](#)

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Martha,

NCBH submitted an exemption request on October 27 that included multiple pieces of individual equipment in one letter and no accompanying documentation. This email requests to withdraw that letter and replace it with three separate exemption request letters along with the corresponding equipment comparison forms: one exemption request letter and comparison form for replacement Stealth Stations, one request letter and comparison for Mazor replacement equipment and one request letter and comparison for O-arm replacement equipment.

Please withdraw the one that is now in my #1 Drafts Administrative Determinations folder and replace it with the three separate exemption requests along with their corresponding comparison form.

Let me know if you have questions.

Thanks,

**Celia C. Inman**

Project Analyst, Certificate of Need

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

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Office: 919-855-3873

[celia.inman@dhhs.nc.gov](mailto:celia.inman@dhhs.nc.gov)

809 Ruggles Drive, Edgerton  
2704 Mail Service Center  
Raleigh, NC 27603

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**From:** Anna Post Mickleberry <apost@wakehealth.edu>

**Sent:** Wednesday, November 4, 2020 5:18 PM

**To:** Inman, Celia C <celia.inman@dhhs.nc.gov>  
**Cc:** Nicole Moore <nsmoore@wakehealth.edu>  
**Subject:** [External] Update - NCBH Request for Confirmation on CON Exemption

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Hi Celia,

Thank you for your time this week. After further discussion following our call on Monday, November 2<sup>nd</sup>, I would like to withdraw the below mentioned letter. On behalf of NCBH, I would like to submit the three (3) letters attached to this email to address each individual equipment request for exemption. I have also attached three (3) separate replacement equipment comparison forms. Please let me know if you need anything else from our end and thank you again.

Kind Regards,  
Anna Mickleberry

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**From:** Anna Post Mickleberry  
**Sent:** Tuesday, October 27, 2020 8:43 AM  
**To:** 'celia.inman@dhhs.nc.gov' <[celia.inman@dhhs.nc.gov](mailto:celia.inman@dhhs.nc.gov)>  
**Cc:** Nicole Moore <[nsmoore@wakehealth.edu](mailto:nsmoore@wakehealth.edu)>  
**Subject:** NCBH Request for Confirmation on CON Exemption

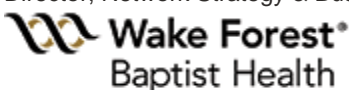
Hi Celia,

I hope this email finds you well. On behalf of NCBH, we would like to submit the attached letter and request for confirmation on CON exemption for plans to replace the existing Medtronic O-Arm, two Stealth Station 7's, and the Mazor Renaissance System. Please do not hesitate to reach out to me with any questions. Thank you.

As a note, I will be going on maternity leave in the next couple of weeks so I've copied my colleague Nicole Moore for awareness and ongoing connection as well. Thank you.

Kind Regards,  
Anna

**Anna Mickleberry, MHA**  
Director, Network Strategy & Business Development



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