



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 #: 3396
Facility Name: North Carolina Baptist Hospital
FID #: 943495
Business Name: North Carolina Baptist Hospital
Business #: 1819
Project Description: Replace existing O Arm imaging device
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 O Arm-02 mobile O Arm imaging device to replace the Medtronic O Arm-01 imaging device, Serial # AIRO-0186 mobile O Arm. 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 O-Arm 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 Medtronic O-Arm model O1 with a new O-Arm model O2. The O-Arm being replaced has reached the end of its useful life and will no longer be supported after December 31st. NCBH has experienced multiple machine faults resulting in down time and repairs during the past year. The O-Arm is a portable imaging device used to provide three-dimensional images in real time during surgery. The current O-Arm was purchased in April of 2011. The current unit will be traded in. The total capital cost of the project is \$471,849. The existing O-Arm 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 O-Arm 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

	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)	Other Major Medical Equipment	Other Major Medical Equipment
Manufacturer	Medtronic	Medtronic
Model number	O Arm – O1	O Arm – O2
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	O Arm – Serial # AIRO-0186	O Arm – Item # B170002000
Is the equipment mobile or fixed?	Mobile	Mobile
Date of acquisition	04/2011	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	\$471,849
Total cost of the equipment	\$486,175	\$471,849
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 average charge per procedure ?	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 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>	maxillofacial, spine, orthopedics (fractures)	NA

Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	maxillofacial, spine, orthopedics (fractures)
--	----	--

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](#)

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](#)

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

celia.inman@dhhs.nc.gov

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

[Twitter](#) | [Facebook](#) | [YouTube](#) | [LinkedIn](#)

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

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report_spam@nc.gov

Hi Celia,

Thank you for your time this week. After further discussion following our call on Monday, November 2nd, 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

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

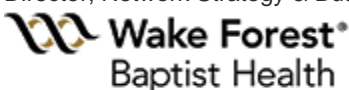
Hi Celia,

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



Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.