



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 23, 2020

Nicole Moore
nsmoore@wakehealth.edu
Anna Post Mickleberry
apost@wakehealth.edu

Exempt from Review – Replacement Equipment

Record #: 3432
Facility Name: High Point Regional Health
FID #: 943251
Business Name: Wake Forest Baptist Health
Business #: 2990
Project Description: Replace existing O-Arm
County: Guilford

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 13, 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, Item # B170002000 mobile O-Arm to replace the Medtronic O-Arm 01, Serial # 00485 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



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VIA EMAIL ONLY

November 23, 2020

Nicole Moore
nsmoore@wakehealth.edu
Anna Post Mickleberry
apost@wakehealth.edu

Exempt from Review – Replacement Equipment

Record #: 3433
Facility Name: High Point Regional Health
FID #: 943251
Business Name: Wake Forest Baptist Health
Business #: 2990
Project Description: Replace existing Stealth Station 7 equipment
County: Guilford

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 13, 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 Stealth Station 8, Item # M072707M014 mobile Stealth Station to replace the existing Medtronic mobile Stealth Station 7, Serial # N00976689. 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

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cc: Radiation Protection Section, DHSR

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From: [Nicole Moore](#)
To: [Inman, Celia C](#)
Cc: [Anna Post Mickleberry](#)
Subject: [External] RE: RE: HPMC Request for Confirmation on CON Exemption
Date: Monday, November 16, 2020 3:17:58 PM
Attachments: [image001.png](#)

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Hi Celia,

Thank you for reaching out. Regarding your inquiries, please see responses below.

1. After further discussion with High Point Regional Hospital surgery department, I have confirmed that only one (1) stealth station (S7 model) is being replaced by two (2) stealth stations (S8 models). This allows 2 surgeons to utilize the O-arm at the same time. The stealth's stay in the room and the O-arm, which does the imaging, moves room to room.
2. Anna Mickleberry is replacing Marisa Barone as the POC for High Point Regional Health, Wake Forest Baptist Health, as well as our other network hospitals, including: Davie Medical Center, Lexington Medical Center, and Wilkes Medical Center. I've include the hospital FID # and License # below for reference.

Hospital Name	License #:	FID #
Lexington Medical Center	H0027	943307
High Point Regional Health	H0052	943251
Davie Medical Center	H0171	080175
NC Baptist Hospital	H0011	943495
Wilkes Medical Center	H0153	943561

Please advise if you have any additional questions. Thank you in advance.

Warm Regards,

Nicole

Nicole Moore, MBA

Strategy & Business Development Associate



Strategy, Growth and Business Development

Medical Center Boulevard \ Winston-Salem, NC 27157

p 336.716.6968 \ m 469.831.6587

nsmoore@wakehealth.edu \ <https://www.WakeHealth.edu>

From: Inman, Celia C <celia.inman@dhhs.nc.gov>

Sent: Monday, November 16, 2020 10:28 AM

To: Nicole Moore <nsmoore@wakehealth.edu>

Cc: Anna Post Mickleberry <apost@wakehealth.edu>

Subject: RE: [External] RE: HPMC Request for Confirmation on CON Exemption
Nicole,

I left a VM for you, but thought an email might be more efficient. I need two things.

1. The equipment comparison sheet only lists one Serial # for a Stealth Station. I need the Serial # of the second Stealth Station being replaced.
2. I need confirmation on whether or not Anna Mickleberry is replacing Marisa Barone as the POC for High Point Regional Health and Wake Forest Baptist Health.

Thanks,

Celia C. Inman

Project Analyst, Certificate of Need

[Division of Health Service Regulation \[secure-web.cisco.com\]](#), Healthcare Planning and Certificate of Need Section

[NC Department of Health and Human Services \[secure-web.cisco.com\]](#)

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#StayStrongNC and get the latest at [nc.gov/covid19 \[nc.gov\]](https://nc.gov/covid19).

Office: 919-855-3873

celia.inman@dhhs.nc.gov

809 Ruggles Drive, Edgerton

2704 Mail Service Center

Raleigh, NC 27603

[Twitter \[secure-web.cisco.com\]](#) | [Facebook \[secure-web.cisco.com\]](#) | [YouTube \[secure-web.cisco.com\]](#) | [LinkedIn \[secure-web.cisco.com\]](#)

From: Nicole Moore <nsmoore@wakehealth.edu>

Sent: Friday, November 13, 2020 3:47 PM

To: Inman, Celia C <celia.inman@dhhs.nc.gov>

Cc: Anna Post Mickleberry <apost@wakehealth.edu>

Subject: [External] RE: HPMC Request for Confirmation on CON Exemption

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Hi Celia,

My apologies for stepping in. While these look very similar, these are new CON exemption letters for High Point Medical Center (vs. previously submitted for NCBH) for an o-arm and stealth station. As a note, we did receive the approvals for NCBH. While Anna is out on maternity leave, please copy me on any communication. Please advise if you have any additional questions. Thank you in advance.

Warm Regards,

Nicole

Nicole Moore, MBA

Strategy & Business Development Associate



Strategy, Growth and Business Development

Medical Center Boulevard \ Winston-Salem, NC 27157

p 336.716.6968 \ m 469.831.6587

nsmoore@wakehealth.edu \ <https://www.WakeHealth.edu>

From: Inman, Celia C <celia.inman@dhhs.nc.gov>

Sent: Friday, November 13, 2020 3:33 PM

To: Anna Post Mickleberry <apost@wakehealth.edu>

Cc: Nicole Moore <nsmoore@wakehealth.edu>

Subject: RE: [External] HPMC Request for Confirmation on CON Exemption

Anna,

Are you asking about these exemptions? I was copied on the approvals that were sent to you on Nov 5. Did you not receive them?

Celia C. Inman

Project Analyst, Certificate of Need

[Division of Health Service Regulation \[secure-web.cisco.com\]](#), Healthcare Planning and

Certificate of Need Section

[NC Department of Health and Human Services \[secure-web.cisco.com\]](#)

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[Know the 3 Ws. Wear. Wait. Wash. \[covid19.ncdhhs.gov\]](#)

#StayStrongNC and get the latest at nc.gov/covid19 [nc.gov].

Office: 919-855-3873

celia.inman@dhhs.nc.gov

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[Twitter \[secure-web.cisco.com\]](#) | [Facebook \[secure-web.cisco.com\]](#) | [YouTube \[secure-web.cisco.com\]](#) | [LinkedIn \[secure-web.cisco.com\]](#)

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

Sent: Friday, November 13, 2020 3:24 PM

To: Inman, Celia C <celia.inman@dhhs.nc.gov>

Cc: Nicole Moore <nsmoore@wakehealth.edu>

Subject: [External] HPMC Request for Confirmation on CON Exemption

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Hi Celia,

Please see the attachments and information below regarding High Point Medical Center's request for CON exemption. Please let us know if we need to provide any further information or documentation. As a note, I will be going on maternity leave starting next week so I've copied my colleague Nicole Moore for awareness and ongoing connection on this request. Thank you!

1. A comparison of the existing and replacement equipment by completing the attached table.
Attached: Replacement Equipment Comparison Forms
2. Documentation that the proposed equipment is comparable to the existing equipment pursuant to 10A NCAC 14C .0303(d). **Attached: Replacement Equipment Comparison Forms**
3. If the replacement equipment will be leased, a copy of the proposed capital lease that transfers substantially all the benefits and risks inherent in the ownership of the equipment to the lessee of the equipment, in accordance with criteria in Generally Accepted Accounting Principles (GAAP). **N/A**
4. If the replacement equipment will be purchased, a copy of the proposed purchase order or

quotation, including the amount of the purchase price before discounts and trade-in allowance. **Attached: Quote from Medtronic**

5. Documentation 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. **Please reference the letters submitted by HPMC requesting confirmation that the project is exempt from CON review, which states that the existing equipment “will be traded in”. Please also reference page 1 of the quote (the trade-in discounts) for additional documentation the that existing units will be traded-in.**
6. Documentation that the existing equipment is currently in use and has not been taken out of service. **The existing equipment is currently in use and has not been taken out of service. Please allow this statement to serve as documentation of such.**

Kind Regards,

Anna

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November 13, 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 High Point Medical Center (FID # 943251; Lic # H0052), Replacement O-Arm Equipment

Dear Ms. Inman,

Pursuant to NC G.S. § 131E-184 (a.7), Exemptions Review, I am writing to request confirmation that the project described below for High Point Medical Center (HPMC) is exempt from review.

High Point Medical Center (“HPMC”) 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. HPMC 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 October of 2011. The current unit will be traded in. The total capital cost of the project is \$562,303. The existing O-Arm will be removed and disposed of by the equipment vendor.

HPMC 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 HPMC 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 #00485	O Arm – Item # B170002000
Is the equipment mobile or fixed?	Mobile	Mobile
Date of acquisition	10/28/2011	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	\$562,303
Total cost of the equipment	Earn Out	\$562,303
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	High Point ORs only	High Point 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	NA
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>	Orthopedic Spine	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	Orthopedic Spine

Date of last revision: 5/17/19



Medtronic USA, Inc
 826 Coal Creek Circle
 Louisville, CO 80027
 www.medtronic.com

EXECUTIVE SUMMARY

PREPARED FOR:

High Point Regional Health, High Point, NC

Quotation Number: 152584-0001109834-4-0

October 09, 2020

All Prices in \$USD

Item Number	Item Description	QTY	Ext. List Price	Ext. Net Price
BI70002000	O-ARM O2 BASE UNIT	1	\$ 656,000.00	\$ 459,200.00
BI75000027	CONFIG BI75000027 O2 SYSTEM NAVIGATION INTERFACE	1	\$ 39,655.00	\$ 27,758.50
BI75000034	CONFIG BI75000034 O2 MULTIPLE FIELD OF VIEW	1	\$ 39,655.00	\$ 27,758.50
BI75000030	CONFIG BI75000030 O2 ADVANCED VIEWING	1	\$ 22,660.00	\$ 15,862.00
BI75000032	CONFIG BI75000032 O2 COLLIMATED AXIAL 3D	1	\$ 16,995.00	\$ 11,896.50
BI75000029	CONFIG BI75000029 O2 HIGH DEFINITION 3D – HD3D	1	\$ 28,325.00	\$ 19,827.50
M072707M015	STEALTHSTATION™ S8 System - New	1	\$ 272,500.00	\$ 190,750.00
9735740	STEALTHSTATION™ SPINE SOFTWARE	1	\$ 92,443.00	\$ 64,710.10
M072707M014	STEALTHSTATION™ S7 to S8 System Trade In	1	\$ 272,500.00	\$ 190,750.00
9735740	STEALTHSTATION™ SPINE SOFTWARE	1	\$ 92,443.00	\$ 64,710.10
Line Item Sub Total			\$ 1,533,176.00	\$ 1,073,223.20
StealthStation S7 Trade-In Discount				(\$ 25,000.00)
O-arm Trade-In Discount				(\$ 40,000.00)
Discounted Subtotal				\$ 1,008,223.20
Shipping, Installation and Handling				\$ 10,000.00
Grand Total				\$ 1,018,223.20

Prices and Terms Valid until October 23, 2020

PREPARED FOR:

High Point Regional Health, High Point, NC

Quotation Number: 152584-0001109834-4-0

October 09, 2020

All Prices in \$USD

Item Number	Item Description	QTY	Ext. List Price	Ext. Net Price
BI70002000	O-ARM O2 BASE UNIT	1	\$ 656,000.00	\$ 459,200.00
	<ul style="list-style-type: none"> • Complete Multidimensional Surgical Imaging System • 3D, multi-plane Fluoro imaging capability • Lateral patient access without compromising mobility • Faster imaging, reduced doses with automated real-time, and pre-set positioning <ul style="list-style-type: none"> • 2K x 1.5K digital flat detector enables higher dynamic range and resolution • Automated multi-plane imaging eliminates manual repositioning or need for a second system (bi-planar Fluoro) <ul style="list-style-type: none"> • System includes the O-arm Imaging Stand, Mobile View Station (MVS) • DICOM 3.0 Compliant. The system supports sending locally created images across the network to another system. It also supports saving images to CD <ul style="list-style-type: none"> • Includes VGA • Includes new 12: 1 X-Ray Grid - Achieves improvement in contrast with higher grid ratio and carbon cover • High Definition 3D - HD3D enabled 			
BI75000027	CONFIG BI75000027 O2 SYSTEM NAVIGATION INTERFACE	1	\$ 39,655.00	\$ 27,758.50
	<ul style="list-style-type: none"> • Unique iso-centric rotation relative to the lateral image in fluoroscopy mode. <ul style="list-style-type: none"> • Rotation around the vertical axis while keeping the anatomy of interest in the imaging field. 			
BI75000034	CONFIG BI75000034 O2 MULTIPLE FIELD OF VIEW	1	\$ 39,655.00	\$ 27,758.50
BI75000030	CONFIG BI75000030 O2 ADVANCED VIEWING	1	\$ 22,660.00	\$ 15,862.00
BI75000032	CONFIG BI75000032 O2 COLLIMATED AXIAL 3D	1	\$ 16,995.00	\$ 11,896.50
BI75000029	CONFIG BI75000029 O2 HIGH DEFINITION 3D – HD3D	1	\$ 28,325.00	\$ 19,827.50
M072707M015	STEALTHSTATION™ S8 System - New	1	\$ 272,500.00	\$ 190,750.00
	Includes: <ul style="list-style-type: none"> • MAIN CART 9735665 STEALTH S8 PREMIUM • CAMERA CART 9735670 STEALTH S8 BASIC • POWER PACK 9735943 STEALTH S8 ENG ONLY 			
9735740	STEALTHSTATION™ SPINE SOFTWARE	1	\$ 92,443.00	\$ 64,710.10

Item Number	Item Description	QTY	Ext. List Price	Ext. Net Price
	<ul style="list-style-type: none"> • Customizable procedure settings for each surgeon • Supports broad portfolio of integrated navigated instruments • Streamlined instrument management interface • Supports auto-registration with O-arm™ Imaging System 			
M072707M014	STEALTHSTATION™ S7 to S8 System Trade In	1	\$ 272,500.00	\$ 190,750.00
	Includes: <ul style="list-style-type: none"> • MAIN CART 9735665 STEALTH S8 PREMIUM • CAMERA CART 9735670 STEALTH S8 BASIC • POWER PACK 9735943 STEALTH S8 ENG ONLY 			
9735740	STEALTHSTATION™ SPINE SOFTWARE	1	\$ 92,443.00	\$ 64,710.10
	<ul style="list-style-type: none"> • Customizable procedure settings for each surgeon • Supports broad portfolio of integrated navigated instruments • Streamlined instrument management interface • Supports auto-registration with O-arm™ Imaging System 			

SALES AND SUPPORT PROPOSAL

Purchase Orders and Signed Proposals can be faxed to: 720-890-3699

This is a Sales & Support Proposal ("Proposal") by and between Medtronic USA, Inc. for its ENT Products and Navigation Products (collectively, "MEDTRONIC") located at 826 Coal Creek Circle, Louisville, Colorado 80027 and High Point Regional Health ("CUSTOMER"), located in High Point NC. The date of the proposal is the date on the first page of this Proposal ('Proposal Date').

Thank you for requesting this Proposal for the O-arm® System and StealthStation® System ("Product"). MEDTRONIC looks forward to partnering with you and the staff at High Point Regional Health to provide for your image guidance needs.

The pricing contained in this proposal is valid until 10/23/2020

I. OFFER AND ACCEPTANCE

This Proposal is an offer by MEDTRONIC to sell the Product described above to the CUSTOMER on the terms of this Proposal and the Medtronic Master Terms and Conditions which are incorporated into this Proposal by reference in their entirety. CUSTOMER accepts this Proposal and places an order for the Product described herein by signing the Proposal at the signature block by an individual authorized to bind the CUSTOMER and returning the Proposal with an appropriate Purchase Order to MEDTRONIC. Upon receipt by MEDTRONIC of the appropriately signed Proposal and Purchase Order, an authorized representative of MEDTRONIC will sign the Proposal on behalf of MEDTRONIC whereupon the Proposal will become a binding Agreement between the parties ("Agreement").

II. PAYMENT TERMS

- Payment to MEDTRONIC by Buyer on invoices from MEDTRONIC under this agreement shall be due within 30 days of the date of the invoice unless otherwise noted in the Additional Terms section.
- FOB Origin. Freight charges are prepaid by MEDTRONIC and added to the CUSTOMER's invoice.

III. INSTALLATION AND IN-SERVICE

The price of the Product includes: installation, complete on-site Product testing and run through.

All site modifications and preparations are the CUSTOMER's responsibility and are to be completed to the specifications given by MEDTRONIC, prior to the date of the installation.

MEDTRONIC is committed to providing CUSTOMER with ongoing technical service and software support on the Product for the Term of this agreement. Details of MEDTRONIC's Customer Support Program are set out in the accompanying Terms and Conditions. However, highlights of this Program are: Software support and maintenance, 24-hour telephone technical assistance, and Software enhancement upgrades to currently owned software packages. The cost of parts associated with the repair of equipment that is out of stated warranty period will be billed to the CUSTOMER.

IV. TRAINING

O-arm® System - MEDTRONIC is committed to providing the necessary training to ensure your staff is capable of operating the O-ARM® System autonomously. All OR Staff, Surgeons, Radiologic Technologists, etc. who will be utilizing the O-ARM® System must be trained by an authorized MEDTRONIC representative. Upon installation of the O-ARM® System, a MEDTRONIC representative will schedule training for up to five (5) business days at a mutually agreed upon date and time at the hospital site. MEDTRONIC may, at its discretion, provide additional on-site training it deems necessary during the warranty period at its expense.

StealthStation® System and Accessories - MEDTRONIC is committed to providing the necessary training to the Trainees on the StealthStation® Navigation System. All employees of CUSTOMER who will be utilizing the StealthStation Navigation System, including OR Staff, Surgeons, Radiologic Technologists, and surgical staff members ("Trainees"), should be trained by an authorized MEDTRONIC representative prior to using the System. Upon installation of the StealthStation® Navigation System, a MEDTRONIC representative will schedule training for Trainees at CUSTOMER's site for no charge on a mutually agreeable date and time. MEDTRONIC may, at its discretion, provide additional on-site

training it deems necessary during the warranty period at its expense.

Upon request by CUSTOMER, MEDTRONIC may also offer additional training for Trainees at MEDTRONIC's StealthStation® University in Louisville, Colorado ("Initial MEDTRONIC Site Training"). For Initial MEDTRONIC Site Training, MEDTRONIC will pre-arrange and pay hotel room fees for up to 10 nights of lodging at MEDTRONIC's designated hotel per CUSTOMER. CUSTOMER shall be responsible for all other fees and costs, including without limitation, travel arrangements, transportation, meals and incidental costs for Trainees.

MEDTRONIC may provide Trainees access to courses at StealthStation® University beyond the Initial MEDTRONIC Site Training at CUSTOMER's sole cost and expense.

*Additional training may involve CE credits for nurses governed by California Board of Nursing. An individual nurse may obtain CEs for a specific course only once per rolling 12 month period.

V. SURGERY SUPPORT

Upon request by the CUSTOMER, MEDTRONIC will provide up to six (6) surgical support visits during the warranty period. MEDTRONIC may, at its discretion and depending on the CUSTOMER circumstance (new hospital staff, new surgical procedure introduced, new accessories or equipment), provide additional surgical support at no charge. The CUSTOMER has the option at any time to purchase through MEDTRONIC guaranteed surgical coverage.

VI. LIMITED WARRANTY

The Product shall be subject to the MEDTRONIC Standard Limited Warranty, applicable to this Product as contained in the Terms and Conditions, for the Term of the agreement. MEDTRONIC SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES, INCLUDING, WITHOUT LIMITATION, THOSE OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

VII. SOFTWARE LICENSE

MEDTRONIC hereby grants to CUSTOMER, and CUSTOMER hereby accepts, a non-transferable, non-exclusive license ("License") to use Licensed Materials in perpetuity if and for so long as CUSTOMER agrees to and abides by the terms and conditions of this Agreement. CUSTOMER may not copy, modify or transfer the Licensed Materials, in whole or in part, except as provided by MEDTRONIC. CUSTOMER may only use the Licensed Materials in connection with the proper usage and operation of the Products.

VIII. TERM OF AGREEMENT

This agreement shall become effective on the date of the last signature in the signature block below ("Execution Date") and shall have a term of one (1) calendar year from the Acceptance Date of the Product ("Term").

IX. CONFIDENTIALITY

All portions of this Proposal are to be considered confidential and are not to be shared with anyone other than an employee or authorized agent of MEDTRONIC, or personnel of CUSTOMER or their representative, unless approved by MEDTRONIC.

X. DELIVERY AND TRANSFER OF OWNERSHIP

Transfer of ownership from MEDTRONIC to CUSTOMER of the Product shall take place immediately upon shipment. The warranty period will commence seven (7) business days following the delivery date, unless otherwise specified in the additional terms section. Installation and training will be scheduled at a mutually agreed upon date.

XI. ADDITIONAL TERMS

- All prices are quoted in US Dollars.
- Please make the Purchase Order (PO) out to Medtronic USA, Inc. (TAX ID# 41-1493213) and reference quotation number on the purchase order. Please return this page signed with the purchase order.
- CUSTOMER hereby grants permission to MEDTRONIC to use its name and identity in its marketing material for the limited purpose of stating only the existence of the agreement.
- The pricing terms and conditions included in this quotation are contingent on CUSTOMER returning their existing O-arm & (1) StealthStation S7 Systems to MEDTRONIC upon receipt of the O-arm & (2) StealthStation S8 Systems.

XII. COMPLETE AGREEMENT

When executed as prescribed herein, this Sales and Support Proposal constitutes a legally binding agreement between the parties. It is the entire agreement between the parties with respect to the subject matter hereof and supersedes all previous proposals, negotiations, representations or commitments between the parties, both written and oral. The terms of this Sales and Support Proposal may be amended only by a writing signed by both parties hereto and shall prevail in the event that there is a conflict or variance with the terms and conditions of any purchase order form or other document submitted by CUSTOMER or with any invoice or other document submitted by MEDTRONIC.

ACCEPTANCE

This agreement sets forth the entire understanding between the parties and supersedes any prior or oral agreements with respect to the matters covered by this agreement. An authorized representative of High Point Regional Health and MEDTRONIC have signed and executed the agreement below.

High Point Regional Health

**Medtronic USA, Inc. for its ENT Products
and Navigation Products**

Signature: _____

Signature: _____

Print Name: _____

Print Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

From: [Inman, Celia C](#)
To: [Waller, Martha K](#)
Subject: FW: [External] HPMC Request for Confirmation on CON Exemption
Date: Friday, November 13, 2020 4:01:45 PM
Attachments: [High Point Regional O2 S8 revised 10-9-20.pdf](#)
[2020 HPMC Stealth Station replacement equipment letter.pdf](#)
[2020 HPMC O-arm replacement equipment letter.pdf](#)
[Replacement Equipment Comparison Form - Stealth Station HPMC.pdf](#)
[Replacement Equipment Comparison Form - O Arm HPMC.pdf](#)

Please record these exemption requests for High Point Regional. Looks similar to NCBH, but this is two exemption requests, one for Stealth Station replacement and one for O-arm replacement.
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

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

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From: Anna Post Mickleberry <apost@wakehealth.edu>
Sent: Friday, November 13, 2020 3:24 PM
To: Inman, Celia C <celia.inman@dhhs.nc.gov>
Cc: Nicole Moore <nsmoore@wakehealth.edu>
Subject: [External] HPMC 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,

Please see the attachments and information below regarding High Point Medical Center's request for CON exemption. Please let us know if we need to provide any further information or documentation. As a note, I will be going on maternity leave starting next week so I've copied my

colleague Nicole Moore for awareness and ongoing connection on this request. Thank you!

1. A comparison of the existing and replacement equipment by completing the attached table. **Attached: Replacement Equipment Comparison Forms**
2. Documentation that the proposed equipment is comparable to the existing equipment pursuant to 10A NCAC 14C .0303(d). **Attached: Replacement Equipment Comparison Forms**
3. If the replacement equipment will be leased, a copy of the proposed capital lease that transfers substantially all the benefits and risks inherent in the ownership of the equipment to the lessee of the equipment, in accordance with criteria in Generally Accepted Accounting Principles (GAAP). **N/A**
4. If the replacement equipment will be purchased, a copy of the proposed purchase order or quotation, including the amount of the purchase price before discounts and trade-in allowance. **Attached: Quote from Medtronic**
5. Documentation 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. **Please reference the letters submitted by HPMC requesting confirmation that the project is exempt from CON review, which states that the existing equipment “will be traded in”. Please also reference page 1 of the quote (the trade-in discounts) for additional documentation the that existing units will be traded-in.**
6. Documentation that the existing equipment is currently in use and has not been taken out of service. **The existing equipment is currently in use and has not been taken out of service. Please allow this statement to serve as documentation of such.**

Kind Regards,
Anna

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.

November 13, 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 High Point Medical Center (FID # 943251; Lic # H0052), Replacement Stealth Station Equipment

Dear Ms. Inman,

Pursuant to NC G.S. § 131E-184 (a.7), Exemptions Review, I am writing to request confirmation that the project described below for High Point Medical Center (HPMC) is exempt from review.

High Point Medical Center (“HPMC”) plans to replace the existing two Medtronic Stealth Station 7’s with Stealth Station 8’s. The Stealth Stations being replaced have reached the end of useful life and will no longer be supported after December 31st. HPMC has experienced multiple machine faults resulting in down time and repairs during the past year. The new Stealth Station 8’s provide guidance in 2D/3D imaging for spine surgical cases. The current two Stealth Station 7’s were purchased in October of 2011. These units will be traded in. The total capital cost of the project is \$510,920.20. The existing two Stealth Station 7’s will be removed and disposed of by the equipment vendor.

HPMC 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 two Stealth Station, 7’s at HPMC 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	Stealth Station – S7	Stealth Station – S8
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	Stealth Station – Serial # N00976689	Stealth Station – Item # M072707M015; M072707M014
Is the equipment mobile or fixed?	Mobile	Mobile
Date of acquisition	10/28/2011	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	\$510,920.20
Total cost of the equipment	Earn Out	\$510,920.20
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	High Point ORs only	High Point 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	NA
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>	Orthopedic spine surgery	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	Orthopedic spine surgery



Medtronic USA, Inc
 826 Coal Creek Circle
 Louisville, CO 80027
 www.medtronic.com

EXECUTIVE SUMMARY

PREPARED FOR:

High Point Regional Health, High Point, NC

Quotation Number: 152584-0001109834-4-0

October 09, 2020

All Prices in \$USD

Item Number	Item Description	QTY	Ext. List Price	Ext. Net Price
BI70002000	O-ARM O2 BASE UNIT	1	\$ 656,000.00	\$ 459,200.00
BI75000027	CONFIG BI75000027 O2 SYSTEM NAVIGATION INTERFACE	1	\$ 39,655.00	\$ 27,758.50
BI75000034	CONFIG BI75000034 O2 MULTIPLE FIELD OF VIEW	1	\$ 39,655.00	\$ 27,758.50
BI75000030	CONFIG BI75000030 O2 ADVANCED VIEWING	1	\$ 22,660.00	\$ 15,862.00
BI75000032	CONFIG BI75000032 O2 COLLIMATED AXIAL 3D	1	\$ 16,995.00	\$ 11,896.50
BI75000029	CONFIG BI75000029 O2 HIGH DEFINITION 3D – HD3D	1	\$ 28,325.00	\$ 19,827.50
M072707M015	STEALTHSTATION™ S8 System - New	1	\$ 272,500.00	\$ 190,750.00
9735740	STEALTHSTATION™ SPINE SOFTWARE	1	\$ 92,443.00	\$ 64,710.10
M072707M014	STEALTHSTATION™ S7 to S8 System Trade In	1	\$ 272,500.00	\$ 190,750.00
9735740	STEALTHSTATION™ SPINE SOFTWARE	1	\$ 92,443.00	\$ 64,710.10
Line Item Sub Total			\$ 1,533,176.00	\$ 1,073,223.20
StealthStation S7 Trade-In Discount				(\$ 25,000.00)
O-arm Trade-In Discount				(\$ 40,000.00)
Discounted Subtotal				\$ 1,008,223.20
Shipping, Installation and Handling				\$ 10,000.00
Grand Total				\$ 1,018,223.20

Prices and Terms Valid until October 23, 2020

PREPARED FOR:

High Point Regional Health, High Point, NC

Quotation Number: 152584-0001109834-4-0

October 09, 2020

All Prices in \$USD

Item Number	Item Description	QTY	Ext. List Price	Ext. Net Price
BI70002000	O-ARM O2 BASE UNIT	1	\$ 656,000.00	\$ 459,200.00
	<ul style="list-style-type: none"> • Complete Multidimensional Surgical Imaging System • 3D, multi-plane Fluoro imaging capability • Lateral patient access without compromising mobility • Faster imaging, reduced doses with automated real-time, and pre-set positioning <ul style="list-style-type: none"> • 2K x 1.5K digital flat detector enables higher dynamic range and resolution • Automated multi-plane imaging eliminates manual repositioning or need for a second system (bi-planar Fluoro) <ul style="list-style-type: none"> • System includes the O-arm Imaging Stand, Mobile View Station (MVS) • DICOM 3.0 Compliant. The system supports sending locally created images across the network to another system. It also supports saving images to CD <ul style="list-style-type: none"> • Includes VGA • Includes new 12: 1 X-Ray Grid - Achieves improvement in contrast with higher grid ratio and carbon cover • High Definition 3D - HD3D enabled 			
BI75000027	CONFIG BI75000027 O2 SYSTEM NAVIGATION INTERFACE	1	\$ 39,655.00	\$ 27,758.50
	<ul style="list-style-type: none"> • Unique iso-centric rotation relative to the lateral image in fluoroscopy mode. <ul style="list-style-type: none"> • Rotation around the vertical axis while keeping the anatomy of interest in the imaging field. 			
BI75000034	CONFIG BI75000034 O2 MULTIPLE FIELD OF VIEW	1	\$ 39,655.00	\$ 27,758.50
BI75000030	CONFIG BI75000030 O2 ADVANCED VIEWING	1	\$ 22,660.00	\$ 15,862.00
BI75000032	CONFIG BI75000032 O2 COLLIMATED AXIAL 3D	1	\$ 16,995.00	\$ 11,896.50
BI75000029	CONFIG BI75000029 O2 HIGH DEFINITION 3D – HD3D	1	\$ 28,325.00	\$ 19,827.50
M072707M015	STEALTHSTATION™ S8 System - New	1	\$ 272,500.00	\$ 190,750.00
	Includes: <ul style="list-style-type: none"> • MAIN CART 9735665 STEALTH S8 PREMIUM • CAMERA CART 9735670 STEALTH S8 BASIC • POWER PACK 9735943 STEALTH S8 ENG ONLY 			
9735740	STEALTHSTATION™ SPINE SOFTWARE	1	\$ 92,443.00	\$ 64,710.10

Item Number	Item Description	QTY	Ext. List Price	Ext. Net Price
	<ul style="list-style-type: none"> • Customizable procedure settings for each surgeon • Supports broad portfolio of integrated navigated instruments • Streamlined instrument management interface • Supports auto-registration with O-arm™ Imaging System 			
M072707M014	STEALTHSTATION™ S7 to S8 System Trade In	1	\$ 272,500.00	\$ 190,750.00
	Includes: <ul style="list-style-type: none"> • MAIN CART 9735665 STEALTH S8 PREMIUM • CAMERA CART 9735670 STEALTH S8 BASIC • POWER PACK 9735943 STEALTH S8 ENG ONLY 			
9735740	STEALTHSTATION™ SPINE SOFTWARE	1	\$ 92,443.00	\$ 64,710.10
	<ul style="list-style-type: none"> • Customizable procedure settings for each surgeon • Supports broad portfolio of integrated navigated instruments • Streamlined instrument management interface • Supports auto-registration with O-arm™ Imaging System 			

SALES AND SUPPORT PROPOSAL

Purchase Orders and Signed Proposals can be faxed to: 720-890-3699

This is a Sales & Support Proposal ("Proposal") by and between Medtronic USA, Inc. for its ENT Products and Navigation Products (collectively, "MEDTRONIC") located at 826 Coal Creek Circle, Louisville, Colorado 80027 and High Point Regional Health ("CUSTOMER"), located in High Point NC. The date of the proposal is the date on the first page of this Proposal ('Proposal Date').

Thank you for requesting this Proposal for the O-arm® System and StealthStation® System ("Product"). MEDTRONIC looks forward to partnering with you and the staff at High Point Regional Health to provide for your image guidance needs.

The pricing contained in this proposal is valid until 10/23/2020

I. OFFER AND ACCEPTANCE

This Proposal is an offer by MEDTRONIC to sell the Product described above to the CUSTOMER on the terms of this Proposal and the Medtronic Master Terms and Conditions which are incorporated into this Proposal by reference in their entirety. CUSTOMER accepts this Proposal and places an order for the Product described herein by signing the Proposal at the signature block by an individual authorized to bind the CUSTOMER and returning the Proposal with an appropriate Purchase Order to MEDTRONIC. Upon receipt by MEDTRONIC of the appropriately signed Proposal and Purchase Order, an authorized representative of MEDTRONIC will sign the Proposal on behalf of MEDTRONIC whereupon the Proposal will become a binding Agreement between the parties ("Agreement").

II. PAYMENT TERMS

- Payment to MEDTRONIC by Buyer on invoices from MEDTRONIC under this agreement shall be due within 30 days of the date of the invoice unless otherwise noted in the Additional Terms section.
- FOB Origin. Freight charges are prepaid by MEDTRONIC and added to the CUSTOMER's invoice.

III. INSTALLATION AND IN-SERVICE

The price of the Product includes: installation, complete on-site Product testing and run through.

All site modifications and preparations are the CUSTOMER's responsibility and are to be completed to the specifications given by MEDTRONIC, prior to the date of the installation.

MEDTRONIC is committed to providing CUSTOMER with ongoing technical service and software support on the Product for the Term of this agreement. Details of MEDTRONIC's Customer Support Program are set out in the accompanying Terms and Conditions. However, highlights of this Program are: Software support and maintenance, 24-hour telephone technical assistance, and Software enhancement upgrades to currently owned software packages. The cost of parts associated with the repair of equipment that is out of stated warranty period will be billed to the CUSTOMER.

IV. TRAINING

O-arm® System - MEDTRONIC is committed to providing the necessary training to ensure your staff is capable of operating the O-ARM® System autonomously. All OR Staff, Surgeons, Radiologic Technologists, etc. who will be utilizing the O-ARM® System must be trained by an authorized MEDTRONIC representative. Upon installation of the O-ARM® System, a MEDTRONIC representative will schedule training for up to five (5) business days at a mutually agreed upon date and time at the hospital site. MEDTRONIC may, at its discretion, provide additional on-site training it deems necessary during the warranty period at its expense.

StealthStation® System and Accessories - MEDTRONIC is committed to providing the necessary training to the Trainees on the StealthStation® Navigation System. All employees of CUSTOMER who will be utilizing the StealthStation Navigation System, including OR Staff, Surgeons, Radiologic Technologists, and surgical staff members ("Trainees"), should be trained by an authorized MEDTRONIC representative prior to using the System. Upon installation of the StealthStation® Navigation System, a MEDTRONIC representative will schedule training for Trainees at CUSTOMER's site for no charge on a mutually agreeable date and time. MEDTRONIC may, at its discretion, provide additional on-site

training it deems necessary during the warranty period at its expense.

Upon request by CUSTOMER, MEDTRONIC may also offer additional training for Trainees at MEDTRONIC's StealthStation® University in Louisville, Colorado ("Initial MEDTRONIC Site Training"). For Initial MEDTRONIC Site Training, MEDTRONIC will pre-arrange and pay hotel room fees for up to 10 nights of lodging at MEDTRONIC's designated hotel per CUSTOMER. CUSTOMER shall be responsible for all other fees and costs, including without limitation, travel arrangements, transportation, meals and incidental costs for Trainees.

MEDTRONIC may provide Trainees access to courses at StealthStation® University beyond the Initial MEDTRONIC Site Training at CUSTOMER's sole cost and expense.

*Additional training may involve CE credits for nurses governed by California Board of Nursing. An individual nurse may obtain CEs for a specific course only once per rolling 12 month period.

V. SURGERY SUPPORT

Upon request by the CUSTOMER, MEDTRONIC will provide up to six (6) surgical support visits during the warranty period. MEDTRONIC may, at its discretion and depending on the CUSTOMER circumstance (new hospital staff, new surgical procedure introduced, new accessories or equipment), provide additional surgical support at no charge. The CUSTOMER has the option at any time to purchase through MEDTRONIC guaranteed surgical coverage.

VI. LIMITED WARRANTY

The Product shall be subject to the MEDTRONIC Standard Limited Warranty, applicable to this Product as contained in the Terms and Conditions, for the Term of the agreement. MEDTRONIC SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES, INCLUDING, WITHOUT LIMITATION, THOSE OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

VII. SOFTWARE LICENSE

MEDTRONIC hereby grants to CUSTOMER, and CUSTOMER hereby accepts, a non-transferable, non-exclusive license ("License") to use Licensed Materials in perpetuity if and for so long as CUSTOMER agrees to and abides by the terms and conditions of this Agreement. CUSTOMER may not copy, modify or transfer the Licensed Materials, in whole or in part, except as provided by MEDTRONIC. CUSTOMER may only use the Licensed Materials in connection with the proper usage and operation of the Products.

VIII. TERM OF AGREEMENT

This agreement shall become effective on the date of the last signature in the signature block below ("Execution Date") and shall have a term of one (1) calendar year from the Acceptance Date of the Product ("Term").

IX. CONFIDENTIALITY

All portions of this Proposal are to be considered confidential and are not to be shared with anyone other than an employee or authorized agent of MEDTRONIC, or personnel of CUSTOMER or their representative, unless approved by MEDTRONIC.

X. DELIVERY AND TRANSFER OF OWNERSHIP

Transfer of ownership from MEDTRONIC to CUSTOMER of the Product shall take place immediately upon shipment. The warranty period will commence seven (7) business days following the delivery date, unless otherwise specified in the additional terms section. Installation and training will be scheduled at a mutually agreed upon date.

XI. ADDITIONAL TERMS

- All prices are quoted in US Dollars.
- Please make the Purchase Order (PO) out to Medtronic USA, Inc. (TAX ID# 41-1493213) and reference quotation number on the purchase order. Please return this page signed with the purchase order.
- CUSTOMER hereby grants permission to MEDTRONIC to use its name and identity in its marketing material for the limited purpose of stating only the existence of the agreement.
- The pricing terms and conditions included in this quotation are contingent on CUSTOMER returning their existing O-arm & (1) StealthStation S7 Systems to MEDTRONIC upon receipt of the O-arm & (2) StealthStation S8 Systems.

XII. COMPLETE AGREEMENT

When executed as prescribed herein, this Sales and Support Proposal constitutes a legally binding agreement between the parties. It is the entire agreement between the parties with respect to the subject matter hereof and supersedes all previous proposals, negotiations, representations or commitments between the parties, both written and oral. The terms of this Sales and Support Proposal may be amended only by a writing signed by both parties hereto and shall prevail in the event that there is a conflict or variance with the terms and conditions of any purchase order form or other document submitted by CUSTOMER or with any invoice or other document submitted by MEDTRONIC.

ACCEPTANCE

This agreement sets forth the entire understanding between the parties and supersedes any prior or oral agreements with respect to the matters covered by this agreement. An authorized representative of High Point Regional Health and MEDTRONIC have signed and executed the agreement below.

High Point Regional Health

**Medtronic USA, Inc. for its ENT Products
and Navigation Products**

Signature: _____

Signature: _____

Print Name: _____

Print Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

From: [Inman, Celia C](#)
To: [Waller, Martha K](#)
Subject: FW: [External] HPMC Request for Confirmation on CON Exemption
Date: Friday, November 13, 2020 4:01:45 PM
Attachments: [High Point Regional O2 S8 revised 10-9-20.pdf](#)
[2020 HPMC Stealth Station replacement equipment letter.pdf](#)
[2020 HPMC O-arm replacement equipment letter.pdf](#)
[Replacement Equipment Comparison Form - Stealth Station HPMC.pdf](#)
[Replacement Equipment Comparison Form - O Arm HPMC.pdf](#)

Please record these exemption requests for High Point Regional. Looks similar to NCBH, but this is two exemption requests, one for Stealth Station replacement and one for O-arm replacement.
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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Anna

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