



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Drexdal Pratt
Division Director

December 18, 2015

Mr. Daniel Goodwin
1960 S. 16th Street
Wilmington, NC 28401

Exempt from Review – Replacement Equipment

Record #: 1820
Facility Name: New Hanover Medical Group Myrtle Grove
FID #: 040426
Business Name: New Hanover Medical Group
Business #: 1307
Project Description: Replace existing CT Scanner at Myrtle Grove
County: New Hanover

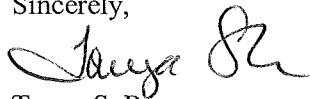
Dear Mr. Goodwin:

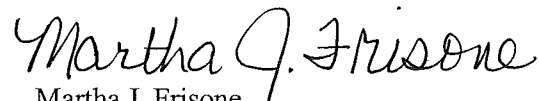
The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of & (Date), the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, Siemens, Scope 16 CT Scanner. This determination is based on your representations that the existing Siemens Emotion 6, serial number 43469 CT Scanner will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

Moreover, you need to contact the Agency's Construction Section to determine if there are 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,


Tanya S. Rupp
Project Analyst


Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Kelli Fisk, Program Assistant, Healthcare Planning



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

An Equal Opportunity/ Affirmative Action Employer



NHRMC Physician Group

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Matthew R. Messier, MD
Margaret W. Pierson, MD
Noah R. Pierson, MD

October 10, 2015

Martha Frisone, Assistant Section Chief
Health Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Notice of Exempt Acquisition by New Hanover Medical Group

Dear Ms. Frisone:

New Hanover Medical Group ("NHMG") proposes to replace its CT scanner at the Myrtle Grove Office location, FID# 040426, CON# 0-7022-04. The purpose of this letter is to notify the Division of Health Service Regulation (the "Department") of NHMG's plans for this equipment replacement. Further, NHMG is requesting confirmation from the Department that the equipment replacement as described does not constitute a new institutional health service, subject to certificate of need ("CON") review.

NHMG is replacing this equipment to increase patient safety regarding radiation dose alerts, where the existing equipment is not compliant and is not able to be upgraded to become compliant with NEMA XR-29 Smart Dose Standards.

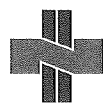
This acquisition is exempt from CON review under N.C.G.S. § 131E-176(14o) because it is for "replacement" equipment. "Replacement equipment" means equipment that costs less than two million dollars (\$2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. N.C.G.S. § 131E-176(22a)

To qualify for this exemption, the replacement equipment must (1) cost less than \$2,000,000, (2) be "comparable" to the equipment it replaces, and (3) replace equipment that is then "sold or otherwise disposed of." NHMG's proposed acquisition qualifies for this exemption, as discussed below.

As set forth in the equipment comparison form, quote and letter of non-compliance with NEMA XR-29 Standards (Exhibit A),



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**NHRMC
Physician Group**

Advancing health care through collaboration

Bus id 1307
FID 040426
NR id 1820

Received by
the CON Section
DEC 7 2015

NHRMC Physician Group

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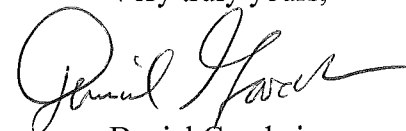
the fair market value of the equipment for this replacement is \$303,360 inclusive of delivery and installation charges. Because there is a trade-in value allowance of \$22,360 for the equipment being removed and some minor construction and assessment costs required for installation, the total cost of this acquisition is \$293,000. The capital cost form for this acquisition is enclosed as Exhibit B.

The current CT scanner in use at NHMG will be traded in and will be taken out of service upon arrival and installation of the replacement unit. See attached letter (Exhibit C) from Siemens indicating compliance with CON requirements for this trade-in unit.

For the reasons set forth above, NHMG respectfully requests that the Agency confirm that this acquisition does not require CON review. If you need any further information on this matter please let me know. I will look forward to hearing from you soon.

With best wishes, I am

Very truly yours,



Daniel Goodwin



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**NHRMC
Physician Group**

Equipment Comparison Form

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	CT Scanner	CT Scanner
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	N/A	N/A
Model Number	Emotion 6	Scope 16
Serial Number	43469	
Provider's Method of Identifying Equipment	Asset Tag #	Asset Tag #
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	2005	December 2015
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	NA	\$ 293,000 (trade-in)
Total Cost of Equipment	\$527,000	\$ 303,360
Fair Market Value of Equipment	NA	\$ 303,360
Net Purchase Price of Equipment	\$527,000	\$ 303,360
Locations Where Operated	5145 S College Rd	5145 S College Rd
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	N/A	Zero
Percent of Change in Per Procedure Operating Expenses (by Procedure)	N/A	Zero
Type of Procedures Currently Performed on Existing Equipment	CT Non-contrasted, contrasted, & angiography exams	CT Non-contrasted, contrasted & angiography exams
Type of Procedures New Equipment is Capable of Performing	Same	Same

SIEMENS

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Nicolette Hendrix - (423) 956-0842

Customer Number: 0000109885

Date: 9/15/2015

Carolinas Healthcare Associates DBA
NEW HANOVER MEDICAL GROUP PA
5145 S COLLEGE RD
WILMINGTON, NC 28412

Siemens Medical Solutions USA, Inc. is pleased to submit the following quotation for the products and services described herein at the stated prices and terms, subject to your acceptance of the terms and conditions on the face and back hereof, and on any attachment hereto.

<u>Table of Contents</u>	<u>Page</u>
SOMATOM Scope (Power configuration) (Quote Nr. 1-BVAGTP Rev. 2).....	2
General Terms and Conditions	6
Warranty Information.....	13

Contract Total: \$281,000
(total does not include any Optional or Alternate components which may be selected)

Proposal valid until 9/30/2015

Estimated Delivery Date: 12/2015

Estimated delivery date is subject to change based upon factory lead times, acceptance date of this quote, customer site readiness, and other factors. A Siemens representative will contact you regarding the final delivery date.

This offer is only valid if a firm, non-contingent order is placed with Siemens and a signed POS contract must accompany the equipment order.

This proposal includes the trade-in of equipment referenced in Trade Sheet Project # 2015-1403.

CT Training Part number: CT_INITIAL_32 (Initial onsite training 32 hrs) costs \$7,800.00
CT Training Part number: CT_ADD_16 (Additional onsite training 16 hours) costs \$4,900.00

Accepted and Agreed to by:

Siemens Medical Solutions USA, Inc.

Carolinas Healthcare Associates DBA
NEW HANOVER MEDICAL GROUP PA

By (sign): _____
Name: Nicolette Hendrix
Title: Account Executive - NGAGE
Date: _____

By (sign): *John A. Gizdic* DBA
Name: *John A. Gizdic*
Title: *President*
Date: *9/29/15*

By signing below, signor certifies that no modifications or additions have been made to the Quotation. Any such modifications or additions will be void.

By (sign): _____

SIEMENS

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Nicolette Hendrix - (423) 956-0842

Quote Nr: 1-BVAGTP Rev. 2

Terms of Payment: 00% Down, 80% Delivery, 20% Installation
Free On Board: Destination

Purchasing Agreement: PREMIER PURCHASING PARTNERS LP

PREMIER PURCHASING PARTNERS LP terms and conditions apply to Quote Nr 1-BVAGTP

SOMATOM Scope (Power configuration)

All items listed below are included for this system:

Qty	Part No.	Item Description
1	14444463	<p>SOMATOM Scope (Power 16-slice)</p> <p>Healthcare facilities around the globe face the challenge of extending high-quality, affordable care to as many people as possible - in the age of shrinking budgets. To succeed, they must improve their financial performance. By doing more with less.</p> <p>The key to mastering this new environment is knowing what really matters: the patients you see every day. To effectively meet their requirements, you need to deliver full clinical capabilities without cutting corners when it comes to performance. But how can you achieve this while keeping costs in check?</p> <p>The all new SOMATOM Scope provides an answer - by focusing on the essence of CT.</p> <p>The SOMATOM Scope Power Configuration adds increased volume coverage and power reserves to provide additional clinical robustness to the scanner and more throughput capabilities.</p>
1	14446680	<p>FAST Planning</p> <p>Immediate, organ-based setting of scan and recon ranges aiming for a safer, faster and more standardized workflow at the scanner. FAST Planning streamlines scan preparation, a vital factor for reducing examination time.</p>
1	WORKSTREA M4D	<p>Workstream4D</p> <p>WorkStream 4D further enhances the already superb workflow of the SOMATOM Emotion CT system by offering direct generation of sagittal, coronal, oblique or double-oblique reconstructed images directly from CT raw data as part of the CT protocol.</p>
1	14446685	<p>Standard IRS</p> <p>IRS (Image Reconstruction System) that pre-processes and reconstructs the CT data and stores the current raw data. Standard reconstruction time: up to 8 images/second. Optional with Recon Plus up to 16 images/second.</p>
1	14446688	<p>IRIS</p> <p>Siemens' proprietary Iterative Reconstruction in Image Space (IRIS) delivers the same image noise reduction as raw-data-model-based iterative reconstruction, but in a fraction of the time - as the raw data is reconstructed only once. This innovative technology is ideal for cost-effective scanners; it significantly enhances spatial resolution while lowering image noise, enabling further dose reductions across a wide range of clinical applications. This is of particular benefit to children and patients requiring multiple scans.</p>
1	14441357	<p>UPS 230 V #AWP</p> <p>Uninterruptible power supply with battery backup for 230 volt networks.</p> <p>The UPS ensures the supply of power to the computer system and color monitor in the event of line voltage fluctuations and brief power failures.</p>
1	14441295	<p>Computer Desk</p> <p>CT desk designed to accommodate the control components and monitor(s).</p>
1	14441296	<p>Computer Cabinet</p> <p>Cabinet to accommodate the computer system and UPS. Designed to match both the computer systems and</p>

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40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Nicolette Hendrix - (423) 956-0842

Qty	Part No.	Item Description
		computer desk.
1	14444364	ELEVATE R 4-/6-slice >Scope Power Elevate from 4-/6-slice configuration system to the SOMATOM Scope Power
1	14441285	Keyboard English Keyboard in the above-mentioned language.
1	14441288	Line connection box Required for connection to supply all networks with line voltages except for 400 volts.
1	14441290	Patient Table Patient Table with motor-driven table height adjustment from 45-83 cm / 17.7-32.7" (at table top), longitudinal movement of the tabletop 160 cm / 63" in increments of 0.5 mm / 0.02", horizontal positioning accuracy +/- 0.25 mm / 0.01". Max. scan range 160 cm / 63". Max. table load: 210 kg / 463 lbs
1	14441291	Foot Switch for Pat.Table control Foot Switch to control the motion (moving in and out) of the patient table, with vertical and horizontal movement.
1	14441331	Table Extension To extend the scan range with patient in the "FEET FIRST" position.
1	CT_PM	CT Project Management A Siemens Project Manager (PM) will be the single point of contact for the implementation of your Siemens equipment. The assigned PM will work with the customer's facilities management, architect or building contractor to assist you in ensuring that your site is ready for installation. Your PM will provide initial and final drawings and will coordinate the scheduling of the equipment, installation, and rigging, as well as the initiation of on-site clinical education.
1	CT_STD_RIG_I NST	CT Standard Rigging and Installation This quotation includes standard rigging and installation of your CT new system. Standard rigging into a room with reasonable access, as determined by Siemens Project Management, during standard working hours (Mon. - Fri./ 8 a.m. to 5 p.m.) It remains the responsibility of the Customer to prepare the room in accordance with the SIEMENS planning documents. Any special rigging requirements (Crane, stairs, etc.) and/or special site requirements (e.g. removal of existing systems, etc.) is an incremental cost and the responsibility of the Customer. All other "out of scope" charges (not covered by the standard rigging and installation) will be identified during the site assessment and remain the responsibility of the Customer.
1	CT_INITIAL_32	Initial onsite training 32 hrs Up to (32) hours of on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	CT_ADD_16	Additional onsite training 16 hours Up to (16) hours of on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist if applicable. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	CTSPER01	CT Slicker Thermoseal seams and flaps deflect fluids, reducing contaminant penetration into the cushion and table. Contaminants are retained on the tabletop or shunted to the floor. Cleanup is faster, more thorough, and contaminant build-up is reduced. Built using heavy, clear, micro matte vinyl, and top grade hook and loop fastening strips (Velcro) to better fit the specified table. Custom vinyl resists tears and minimizes radiologic interference. Latex free. Set includes CT Skirts. Includes warranty from RADSCAN Medical.

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40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Nicolette Hendrix - (423) 956-0842

Qty	Part No.	Item Description
1	4SPAS014	Low Contrast CT Phantom & Holder
	PSPD250480Y	
1	3K	Surge Protective Device (SPD)
	CARE_DOSE4	
1	D	CARE Dose4D CARE Dose4D delivers the highest possible image quality at the lowest possible dose for patients - maximum detail, minimum dose. Adaptive dose modulation for up to 60% dose reduction
1	NEMA_XR-29	NEMA_XR-29 Standard This system is in compliance with NEMA XR-29 Standard Attributes on CT Equipment Related to Dose Optimization and Management, also known as Smart Dose.
1	UFC_DETECT OR	UFC Detector Ultra Fast Ceramics (UFC) technology is a unique type of scintillation technology material that quickly and efficiently transforms radiation from the X-ray tube into light signals. Its superb overall quantum efficiency and unique short afterglow enable time-critical X-ray detection at low doses and extremely fast data collection.
1	CT_TRADE_IN _ALLOW	CT Trade-in-Allowance Siemens Emotion 6 Project# 2015-1403 Serial# 43469 DeInstall 12/2015 Valid until 10/7/2015 at \$22,360
1	CT_ADDL_RIG GING	Additional Rigging CT \$750
1	14441297	HeartView CT #16 Slice Clinical application package used with the SOMATOM Scope Power Configuration for optimized ECG-controlled data acquisition/image reconstruction and evaluation of cardiac data sets for the quantification of coronary calcifications. The package includes hardware and software components, with ECG device integrated in the CT gantry. The use of the software of this option is restricted to a single system unit.
1	14441304	syngo Calcium Scoring CT #AWP Dedicated application for the quantification of calcifications in CT images. For best results, CT images acquired with HeartView CT by ECG-synchronized imaging should be used. The Calcium Scoring software calculates various scores (Agatston score, volume score and calcium mass) to assess the risk of a cardiac infarct within user-defined regions for up to four coronary arteries.
1	14441299	ECG cable IEC2 ECG cable, IEC2 (AHA/US color coding).
1	14441332	Head and Arm Support For comfortable head and arm positioning during chest, abdominal and lumbar spine examinations. The positioning aid can be inserted into the top of the patient table.

System Total: \$281,000

SIEMENS

Carolina Healthcare Associates Inc
5145 S College Rd
Wilmington, NC 28412

The NEMA XR-29 Smart Dose Standard establishes a baseline for CT technology. Starting in 2016, there will be a 5% penalty on Medicare reimbursements for diagnostic CT imaging on noncompliant technology. In 2017 and beyond, the penalty escalates to 15% for diagnostic CT imaging on noncompliant technology. In order to comply, a CT scanner must have four features:

- DICOM Radiation Dose Structured Reporting capability
- Dose Check standard (NEMA XR-25)
- Automatic Exposure Control capability
- Reference adult and pediatric protocols

We have determined that 90% of our non-end-of-support CT¹ installed base either meets or can be upgraded to comply with NEMA XR-29 with a free of charge upgrade.²

Here is the status of your current Siemens CT portfolio

Cannot be upgraded to comply with NEMA XR-29:

Functional Location Number	System
400-159200	SOMATOM Emotion 6

Who can you call?

Should you have questions, or require additional information, please feel free to contact us at 1-888-826-9702.

Sincerely,



Murat Gungor
Vice President, CT and Radiation Oncology Business Management

¹Non end-of-support SOMATOM CT systems include: SOMATOM Force, SOMATOM Definition Flash, SOMATOM Definition Edge, SOMATOM Definition AS, SOMATOM Perspective, SOMATOM Scope, SOMATOM Emotion.

²Free of charge upgrade applies to customers with non-end of support systems that are on Siemens service contract. In other cases, software-only is provided free of charge, customers may incur installation costs if they elect for Siemens to perform the upgrade.

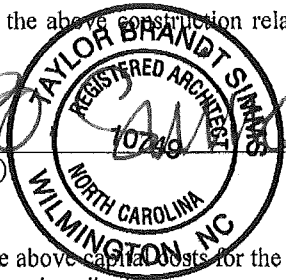
PROPOSED CAPITAL COSTS

Project Name: NHMG CT Replacement
Proponent: New Hanover Medical Group

A. <u>Site Costs</u>			
(1)	Full purchase price of land		\$ _____
	Acres _____ Price per Acre	\$ _____	
(2)	Closing costs		\$ _____
(3)	Site Inspection and Survey		\$ _____
(4)	Legal fees and subsoil investigation.		\$ _____
(5)	Site Preparation Costs		
	Soil Borings	\$ _____	
	Clearing-Earthwork	\$ _____	
	Fine Grade For Slab	\$ _____	
	Roads-Paving	\$ _____	
	Concrete Sidewalks	\$ _____	
	Water and Sewer	\$ _____	
	Footing Excavation	\$ _____	
	Footing Backfill	\$ _____	
	Termite Treatment	\$ _____	
	Other (Specify)	\$ _____	
	Sub-Total Site Preparation Costs		\$ _____
(6)	Other (Specify)		\$ _____
(7)	Sub-Total Site Costs		\$ _____
B. <u>Construction Contract</u>			
(8)	Cost of Materials		
	General Requirements	\$ _____	
	Concrete/Masonry	\$ _____	
	Doors & Windows/Finishes	\$ _____	
	Thermal & Moisture Protection	\$ _____	
	Equipment/Specialty Items	\$ _____	
	Mechanical/Electrical	\$ _____	
	Other (Specify)	\$ _____	
	Sub-Total Cost of Materials		\$ _____
(9)	Cost of Labor		\$ _____
(10)	Other (Specify)		\$ _____
(11)	Sub-Total Construction Contract		<u>\$10,000</u>
C. <u>Miscellaneous Project Costs</u>			
(12)	Building Purchase		\$ _____
(13)	Fixed Equipment Purchase/Lease		<u>\$281,000 (with trade-in)</u>
(14)	Movable Equipment Purchase/Leas		\$ _____
(15)	Furniture		\$ _____
(16)	Landscaping		\$ _____
(17)	Consultant Fees		
	Architect and Engineering Fees	\$ _____	
	Legal Fees	\$ _____	
	Market Analysis	\$ _____	
	Other (Specify)	\$2,000 (Physicist assessment)	
	Sub-Total Consultant Fees		\$ _____
(18)	Financing Costs (e.g. Bond, Loan, etc.)		\$ _____
(19)	Interest During Construction		\$ _____
(20)	Other (Specify)		\$ _____
(21)	Sub-Total Miscellaneous		<u>\$283,000</u>
D.	Total Capital Cost of Project		<u>\$293,000</u>

I certify that, to the best of my knowledge, the above construction related costs of the proposed project named above are complete and correct.

Taylor Brandt



(Signature of Licensed Architect or Engineer)

I assure that, to the best of my knowledge, the above capital costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

Daniel Goodwin

Daniel Goodwin

Vice President, NHRMC Physician Group

Exhibit C

SIEMENS

Medical Solutions USA, Inc

Kim Hood, RT (R) (CT) CRA
Radiology Manager-CHA
New Hanover Medical Group
NHRMC Physician Group
5145 S College Road
Wilmington, NC 28412

Name	Robert Ferrero Zone Finance Vice President, Southeast 4800 North Point Parkway Alpharetta, GA 30022
Tel.	
Fax.	+1 (770) 369-8232
Mobile	+1 (610) 551-3795
E-mail	Robert.ferrero@siemens.com
Date	October 19, 2015

The purpose of this letter is to document that Siemens Medical Solutions USA, Inc. will be responsible for removing the existing Siemens CT scanner system at your site. The de-installation and removal is included as part of the upcoming installation of the Siemens Scope CT scanner system as documented in Quotation No. 1-BVAGTP Rev. 2, that was executed by the Parties on September 29, 2015.

As detailed in the Quotation terms, Siemens will coordinate with customer regarding the de-installation and removal of the system.

Please do not hesitate to call with any further question.

Sincerely,



Robert Ferrero
Zone Finance Vice President
Southeast Zone

Siemens Medical Solutions USA, Inc.
Corporate Headquarters 51 Valley Stream Parkway
Malvern, PA 19355

1-888-826-9702
www.usa.siemens.com/medical