



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

August 29, 2017

Lisa Griffin
Novant Health, Inc.
2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

Exempt from Review – Replacement Equipment

Record #: 2373
Facility Name: Novant Health Forsyth Medical Center
FID #: 923174
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Replace existing C-Arm equipment
County: Forsyth


Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of August 25, 2017, 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 Siemens Artis ZEE fixed C-Arm equipment to replace the Siemens Axiom Artis fixed C-Arm equipment, Serial # 1322. 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 Construction and Acute and Home Care Licensure and Certification Sections 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
Project Analyst


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

cc: Construction Section, DHSR
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION
WWW.NCDHHS.GOV

TELEPHONE 919-855-3873

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



August 25, 2017

Via Email

Celia Inman, Project Analyst, Certificate of Need
N.C. Department of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

**NOVANT
HEALTH**



2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

Re: Novant Health, Inc. – Novant Health
Forsyth Medical Center
Replacement of C-Arm Equipment
Winston-Salem, NC (Forsyth County)

Dear Ms. Inman:

Novant Health, Inc. and Novant Health Forsyth Medical Center (“NHFMC”) intend to replace an existing fixed C-arm unit currently located at the main campus of NHFMC in Winston-Salem, North Carolina. The existing unit was purchased in 2002 and is past its useful life. NHFMC will acquire a new Siemens Artis C-arm and the existing unit will be removed by the vendor as indicated on pPage 1 of the Equipment Quote included as **Attachment A**. As part of the equipment cost, the vendor will provide onsite clinical training for the equipment. The total capital cost for the proposed replacement equipment project is estimated to be \$1,163,733,45¹. See **Attachment B** – Project Capital Cost.

The proposed project meets the definition of “replacement equipment” found in G.S. 131E-176(22a) and 10A N.C.A.C 14C.0303 for the following reasons:

- (1) NHFMC will replace the existing C-arm unit with the proposed C-arm unit that is functionally similar and will be used for the same diagnostic purposes, although it possesses expanded capabilities due to technological improvements.
- (2) The proposed C-arm unit will not be used to provide a new health service.
- (3) The acquisition of the proposed C-arm unit will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.
- (4) NHFMC seeks to replace comparable medical equipment currently in use at project cost less than \$2 million.
- (5) The existing equipment was not purchased second-hand nor was the existing equipment leased.

In support of our request, please find attached:

Attachment A – Vendor Equipment Quote
Attachment B – Project Capital Cost
Attachment C – NC CON Equipment Comparison chart

¹ The project cost does not include sales, property or excise taxes as NHFMC is not subject to these taxes as a non-profit, tax-exempt organization.

Ms. Celia Inman
Novant Health Forsyth Medical Center – Replacement of C-arm Equipment
Page 2

NHFMC's acquisition of the replacement C-arm unit does not require a certificate of need because none of the definitions of "new institutional health services" set forth in N.C.G.S. Section 131E-176(16) apply to the proposed project. As outlined above, the total cost for the project is \$1,163,733,45. The proposed capital cost includes equipment, as well as studies, surveys, designs, plans, working drawings, specifications, construction installation and other activities essential to making the equipment operational.

Based on the information provided, please confirm that NHFMC's replacement equipment request does not constitute a new institutional health service and is exempt from certificate of need review.

If you need additional information, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "Lisa Griffin". The signature is written in a cursive style with a large initial "L".

Lisa Griffin
Manager, Certificate of Need
Novant Health, Inc.

Enclosures

Cc: Barbara Freedy, Director, CON, Novant Health

**ATTACHMENT A –
Equipment Quote**



Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355
Fax: (866) 309-6967

SIEMENS REPRESENTATIVE
Stuart Waddey - (919) 605-9227

Customer Number: 0000006208

Date: 8/1/2017

FORSYTH MEDICAL CENTER
3333 SILAS CREEK PARKWAY
WINSTON-SALEM, NC 27103

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>
Artis zee multi-purpose (Quote Nr. 1-JLUWSF Rev. 2)	3
General Terms and Conditions	6
Warranty Information	14
Detailed Technical Specifications	16
Cut Sheets	following page 23

Contract Total: \$569,388

Proposal valid until 12/31/2017

Estimated Delivery Date: 8/2018

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 proposal includes the trade-in of equipment referenced in Trade Sheet Project # 2017-0958

This offer is only valid if firm, non-contingent orders for the following quotes are simultaneously placed with

Siemens:
1-JLUWSF
1-HQ0V6R

The biomedical educational offering in this quote must be completed by the later of (12) months from purchase of training or if applicable, completion of installation. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.

Quotation is contingent on Customer receiving State CON Approval.

Accepted and Agreed to by:

Siemens Medical Solutions USA, Inc.

FORSYTH MEDICAL CENTER

By (sign): _____
Name: Stuart Waddey

By (sign): _____
Name: _____



Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355
Fax: (866) 309-6967

SIEMENS REPRESENTATIVE
Stuart Wadley - (919) 605-9227

Title: Account Executive
Date: _____

Title: _____
Date: _____

***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 Medical Solutions USA, Inc.
 40 Liberty Boulevard, Malvern, PA 19355
 Fax: (866) 309-6967

SIEMENS REPRESENTATIVE
 Stuart Wadley - (919) 605-9227

Quote Nr: 1-JLUWSF Rev. 2

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

Purchasing Agreement: VIZIENT SUPPLY LLC

VIZIENT SUPPLY LLC terms and conditions apply to Quote Nr 1-JLUWSF

Artis zee multi-purpose

All items listed below are included for this system: (See Detailed Technical Specifications at end of Proposal.)

Qty	Part No.	Item Description
1	14446016	<p>Artis zee MP BK mounting on right</p> <p>The Artis zee MP right now features PURE(r). PURE adds smooth interaction to Siemens' smart technologies. It is designed to boost productivity and enhance outcomes for certain clinical applications while increasing image quality and reducing dose.</p> <p>The Artis zee MP is a multi-functional C-arm stand with right suspension (mounting) of the positioning table and display suspension system with TFT Live- and Ref-Monitors.</p> <p>The digital C-arm X-ray system for fluoroscopy as well as diagnostic and interventional angiography has an angio collimator and a high-resolution as40 flat detector. The powerful 100 kW HF X-ray generator and MEGALIX Cat Plus X-ray tube (3-focus tube with flat emitter technology) are the prerequisites for excellent image quality. The C-arm and patient table are tiltable and height-adjustable units and can be moved relative to the patient in cranio-caudal and orbital direction. Isocentric object positioning is achieved through independent height adjustment of the tabletop, which can additionally be adjusted in longitudinal and transverse direction. Programmed system positions allow fast examination procedures.</p> <p>Digital acquisition technology with up to 7.5 f/s in 1k/12 bit matrix is available.</p> <p>The complete CARE+CLEAR package offers optimal image quality at the lowest reasonable dose.</p>
1	14432947	<p>Fluoro Loop</p> <p>Storage and review of dynamic fluoroscopic sequences (Fluoro Loop). This saves an additional acquisition and reduces dose. The maximum storable fluoroscopic time depends on the selected pulse rate, e.g. 34 s at 30 p/s, 68 s at 15 p/s.</p>
1	14440394	<p>DSA acquisition mode</p> <p>Digital Subtraction Angiography with frame rates of 0.5 to 7.5 f/s, including pixel shift, remask, roadmap, peak opacification for iodine contrast (MaxOpac), and CO2 contrast (MinOpac); adding of the anatomical background (landmark) from 0 to 100%.</p> <p>It also includes CLEARmap and CLEARmatch.</p>
1	14432950	<p>DICOM RIS-Modality Worklist</p> <p>Import of patient/examination data from an external RIS/HIS patient management system with DICOM MWL (Modality Worklist).</p>

Siemens Medical Solutions USA, Inc.
 40 Liberty Boulevard, Malvern, PA 19355
 Fax: (866) 309-6967

SIEMENS REPRESENTATIVE
 Stuart Waddey - (919) 605-9227

Qty	Part No.	Item Description
1	14409422	AX ELEVATE #O ANGIO/CARD AT Elevate #O program for angiography and card-angiography systems installed prior to 2004 or go end of support until 2016 and which will be replaced by a new Artis Q or Artis Q.zen system, Artis one and Artis zee
1	AXA_ADD_12	Additional onsite training 12 hours Up to (12) 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	AXA_ADD_24	Additional onsite training 24 hours Up to (24) 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	AXA_ADD_32	Additional onsite training 32 hours 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 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	AXA_ECLASS	e.class-Virtual Instructor Led Training AXA_ECLASS Tuition for up to (4) imaging professionals to participate in a Siemens instructor led virtual class. The virtual setting allows the participant to benefit from classroom training without the need to travel to a Siemens training center. 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	AXA_O_SINGL E_PLANE	Elevate O Single Plane
1	AXA_ELVOFC MP_DEINS	Elevate O Deinstallation Ceiling-Flr-MP
1	AXA_ELVOFC MP_DEOFF	Elevate O Deinstal Ceiling-Flr-MP Offset
1	NT60010635	Blue anti-fatigue floor mat for hospital
1	AS11155036	Lower Body Prot. UT50 Artis zee MP Modular lower body x-ray protection for Artis zee MP. Offers protection for physicians and medical staff e.g. in the gastrointestinal work environment.
1	AXA_RIG_ZEE SP_STD	Standard Rigging zee SP
1	AXA_ADDL_RI GGING	Additional Rigging AXA \$5,700
1	AXA_BIOMD_T RN	Biomedical Training AXA - XX2SYNGO - Syngo with Multimodality Workstation - (5 days) \$10,050.00 This educational offering must be completed by the later of (12) months from purchase of training or if applicable, completion of installation. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	AXA_BIOMD_T RN	Biomedical Training AX2ARTZPUR - Artis Zee systems (with/without PURE) - (15 days) \$27,300.00 This educational offering must be completed by the later of (12) months from purchase of training or if applicable, completion of installation. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.

System Total: \$569,388

**ATTACHMENT B –
Project Capital Cost Form**

PROJECT CAPITAL COST
FMC – C-Arm Equipment/Multi-Purpose Room

A. Site Costs		
	(1) Full purchase price of land	
	(2) Closing Costs	
	(3) Site Inspection & Survey	
	(4) Legal Fees & subsoil investigation	
	(5) Site Preparation Costs	
	(6) Other:	
	(7) Sub-Total Site Costs	N/A
B. Construction Contract		
	(8) Cost of Materials*	\$473,998.15
	(9) Cost of Labor	
	(10) Other: <i>Construction Contingency</i>	\$42,310.30
	(11) Sub-Total Construction Contract	\$516,308.45
C. Miscellaneous Project Costs		
	(12) Building Purchase	
	(13) & (14) Fixed Equipment Purchase/Lease + Movable Equipment Purchase/Lease*	\$605,000
	(14a) Information Technology	\$8,500
	(15) Furniture & Signage	\$3,500
	(16) Landscaping	
	(17) Consultant Fees (CON Consultant)	
	Other:	
	Sub-Total Consultant Fees	
	(18) Financing Costs (Bond, Loan, etc.)/Imputed Interest	
	(19) Interest During Construction	
	(20) Other (Specify): <i>Project Contingency</i>	\$30,425
	(21) Sub-Total Miscellaneous	\$647,425
D. Total Capital Cost of Project	(22) Total Capital Cost of Project -Sum above Subtotals for Rows (11) & (21)	\$1,163,733.45

**ATTACHMENT C –
NC Equipment Comparison Form**

Equipment Comparison Form

FMC C-Arm Equipment	Existing Equipment	Replacement Equipment
Type of Equipment (List Each Component)	Fixed C-arm	Fixed C-arm
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	N/A	N/A
Model Number	Axiom Artis	Artis ZEE
Serial Number	1322	TBD
Provider's Method of Identifying Equipment	Internal Asset Numbering System	Internal Asset Numbering System
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	October 2002	TBD
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title to be held by Forsyth Medical Center upon purchase
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project	\$931,281	\$1,163,733.45
Total Cost of Equipment	\$731,281	\$605,000
Fair Market Value of Equipment	\$0	\$605,000
Net Purchase Price of Equipment	\$731,281	\$605,000
Locations Where Operated	Forsyth Medical Center – Diagnostic Radiology Dept.	Forsyth Medical Center – Diagnostic Radiology Dept.
Number of Days in Use/To be Used in NC per Year	365	365
Percent of Change in Patient Charges by Procedure	N/A	No increase
Percent of Change in Per Procedure Operating Expenses by Procedure	N/A	No increase
Type of Procedures Currently Performed on Existing Equipment	Minimal Invasive Procedures- PICCs, LPs, Joint Injections	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	Minimal Invasive Procedures- PICCs, LPs, Joint Injections