



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

August 28, 2017

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

Exempt from Review – Replacement Equipment

Record #: 2372
Facility Name: Novant Health Forsyth Medical Center
FID #: 923174
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Replace existing x-ray 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 Uroskop Omnia Max x-ray equipment to replace the GE Uroview 2800 x-ray equipment, Serial # P4-0120-L. 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

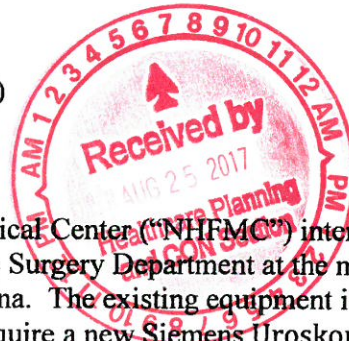
Via Email

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



2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

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



Dear Ms. Inman:

Novant Health, Inc. and Novant Health Forsyth Medical Center (“NHFMC”) intend to replace an existing x-ray unit currently located in the Surgery Department at the main campus of NHFMC in Winston-Salem, North Carolina. The existing equipment is over 15 years old and past its useful life. NHFMC will acquire a new Siemens Uroskop Omnia Max. See **Attachment A** for the Equipment Quote. As part of the equipment cost, the vendor will provide onsite clinical training for the equipment. Also included in **Attachment A** is the quote from First Call Parts to remove and dispose of the existing unit. The total capital cost for the proposed replacement equipment project is estimated to be \$765,625.80¹. 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 x-ray unit with the proposed x-ray 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 x-ray unit will not be used to provide a new health service.
- (3) The acquisition of the proposed x-ray 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 & Vendor Removal 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 – X-Ray Equipment Replacement
Page 2

NHFMC's acquisition of the replacement x-ray 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 \$762,625.80. 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,



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

Enclosures

Cc: Barbara Freedy, Director, CON, Novant Health



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

SIEMENS REPRESENTATIVE
Andy Greuling

Customer Number: 0000006208

Date: 7/25/2017

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>
Uroskop Omnia Max (Quote Nr. 1-H9P1DI Rev. 7)	3
General Terms and Conditions	7
Warranty Information	15
Cut Sheets	following page 17

Contract Total: \$368,465

Proposal valid until 1/30/2018

Estimated Delivery Date: 1/30/2018

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.

Pricing is contingent on Customer accepting delivery of the Products within 4 months of order date. Pricing is subject to change if this delivery/installation date is not met.

This Quotation is specific to FORSYTH MEDICAL CENTER, and contains information which is confidential and proprietary to Siemens, including but not limited to discounts and pricing. The Customer may not distribute or disclose this quotation or any portion hereof to, or discuss any of the information (including pricing) contained herein with, any other customer or consultant, buying group, or other third party.

This order is contingent upon CON approval from the State of North Carolina. If CON approval is not granted, customer may cancel this order without penalty.

Upon receipt of CON approval from the State, please notify Siemens in writing so that equipment delivery can be scheduled.

Accepted and Agreed to by:

Siemens Medical Solutions USA, Inc.

FORSYTH MEDICAL CENTER

By (sign): _____
Name: Andy Greuling

By (sign): _____
Name: _____



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

SIEMENS REPRESENTATIVE
Andy Greuling

Title: Product Sales 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
Andy Greuling

Quote Nr: 1-H9P1DI Rev. 7

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-H9P1DI

Uroskop Omnia Max

All items listed below are included for this system:

Qty	Part No.	Item Description
1	04459454	Cable storage item Cable storage compartment for accommodating surplus cable lengths. The cable storage compartment is fitted to the side of the generator cabinet.
1	04459595	Endoscopy shelf , left
1	14409832	HD VideoManager This plug and play interface displays live and reference images from endoscopy, ultrasound, and all DICOM modalities - next to your radiography or fluoroscopy images. Even HD (high definition) endoscopy is supported.
1	14409937	19" TFT color monitor 19" Flat display in TFT technology for the user interface of the imaging system and display of the X-ray live image in the control room.
1	14409876	Handheld control Additional hand-held control for the control room for remote control of the system. All table movements, travel and park position of the X-ray system, park position of the scattered radiation grid, zoom levels, collimator setting. Individually configurable patient transfer and standard working position. Memory functions for table positions and collimator setting. Storage of fluoroscopy images, navigation in the patient image and reference folder and image reversal. Switch between reference / endoscopy and ultrasound modes. Change of organ program. Automatic fluoroscopy control. The hand-held control attaches magnetically to the control panel in the control room.
1	14409876	Handheld control Additional hand-held control for the control room for remote control of the system. All table movements, travel and park position of the X-ray system, park position of the scattered radiation grid, zoom levels, collimator setting. Individually configurable patient transfer and standard working position. Memory functions for table positions and collimator setting. Storage of fluoroscopy images, navigation in the patient image and reference folder and image reversal. Switch between reference / endoscopy and ultrasound modes. Change of organ program. Automatic fluoroscopy control. The hand-held control attaches magnetically to the control panel in the control room.
1	14436612	Keyboard; US Standard keyboard
1	14409875	CAREMAX Measuring chamber integrated into the collimator housing for measuring the dose area product. The measured values for the dose area product, the accumulated skin entrance dose of the patient (calculated for

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Qty	Part No.	Item Description
		30 cm distance from the table, in mGy or as percentage of the configurable limit value) and/or the incident dose rate during fluoroscopy are displayed on the live image monitors.
1	14402265	Fluoroloop
1	14443217	DVD-Recording Direct output of fluoroscopy and image series on DVD recorder.
1	14402266	Harmonization
1	14402268	Dicom Query/Retrieve Retrieval of archived images, created with the FLUOROSPOT Compact, from a digital archive or from a workstation, in DICOM XRF, XA, CR, or SC format.
1	14402269	Dicom Worklist/MPPS
1	14402270	Dicom Print
2	04459488	Holder for plastic drain bag
1	04459389	Leg support Coxafix (1 pair)
1	SPU_STD_RIG	SPU Standard Rigging & Installation
1	G_INST	
1	XPU_INITIAL_3 2	Initial onsite trng 32 hrs - FMV \$7900 Up to (32) hours of on-site clinical education training, scheduled consecutively 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	XPU_FOLLOW UP_16	Follow-up Training 16 hours Up to (16) hours of follow-up on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. 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	AMFABSLTE	Armboard with trigger adjustment
1	AMOA1004X10 RA	1 in armboard pad
1	AEZT97130043 12W	Cable tubing 3 1/2# RD w/Velcro
2	CF507505	CF Urology drain bag (20) Urology Drain bag designed specifically for the Siemens Uroskop Access. Made of Durable Vinyl, this drain bag utilizes an under-buttocks flap to direct fluids into the bag. Sterile, individually pouched. (case of 20)
1	SPC_ADDL_RI GGING	Additional Rigging SPC \$3,600
1	CF507506	FootswitchCover f.Uro.Access24x20in Q100
1	14436609	Uroskop Omnia Max; Left Uroskop Omnia Max is a high-end fluoroscopy and radiography system for urological diagnosis and therapy. The system has a 43 cm x 43 cm dynamic flat detector, enabling survey images of the entire urinary tract. The unique system design with curved tube column and two TFT color monitors on a swiveling articulated spring arm enables unrestricted patient access from all four sides of the table. The optional HD Video manager offers numerous interfaces for simultaneous display of endoscopy and ultrasound images for example with radiography and fluoroscopy images, as well as video transmission, e.g., of live radiography images to external video urodynamic workplaces
1	14409834	HD EndoStore Store together what belongs together: images from all modalities can be stored together with X-rays as DICOM images in one patient folder. Just one more click and they will be sent to a PACS as a bundled package - for fast retrieval anytime.

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SIEMENS REPRESENTATIVE
Andy Greuling

Qty	Part No.	Item Description
1	14404737	Multifunctional footswitch Advanced Ergonomic footswitch for controlling table lift, table tilt, table longitudinal and transverse movement, rocker switch for longitudinal movement of the X-ray system, switch between X-ray/endoscopy/ ultrasound image, storage of endoscopic image snapshot, last fluoroscopic image (LIH), and rocker switch for fluoroscopy/radiography.

System Total: \$368,465

FIRST CALL PARTS
 1351 Southside Drive
 Salem, VA 24153



tel: 800.782.0003 fax: 540.375.6602

SALES QUOTE	
SQ-150354	8/15/2017



Customer		Contact		Ship To		
Novant Health, Inc. Lynn Bridges Attn: Accounts Payable CEMP 1578 Roger Dale Carter Drive KANNAPOLIS NC 28081 UNITED STATES		Novant Health, Inc. Dwight Biggs PO Box 25686 WINSTON SALEM NC 27114 UNITED STATES Tel: (336)601-3420				
Account	Terms	Due Date	Account Rep	Schedule Date		
10124	NET 30	9/14/2017	Timothy Smith	8/15/2017		
Quotation	PO #	Reference	Ship VIA	Page	Printed	
SQ-150354	Pending			1	8/15/2017 2:23:26PM	
L Item	Description	Qty	Price	UM	Discount	Amount
1 MISC	Removal and disposal of an OEC Uroview 2800 located at Forsyth Medical Center	1	\$3,000.00	EA		\$3,000.00
<p>All parts are sold on an exchange basis unless otherwise specified at the time of sale. Please return your core exchange with a valid return material authorization form to prevent additional billing.</p> <p>Thank you for your purchase. Make checks payable to "First Call Parts, Inc." and remit to: 1351 Southside Drive Salem, VA 24153 (800) 782-0003</p> <p>No returns are permitted without a valid return material authorization number.</p>		Tax Details EXRMPY \$0.000		Taxable \$0.00 Total Tax \$0.00 Exempt \$3,000.00 Total \$3,000.00 Balance \$3,000.00		

**ATTACHMENT B –
Project Capital Cost Form**

PROJECT CAPITAL COST
FMC - Replacement of X-Ray Equipment in OR

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*	\$301,716.40
	(9) Cost of Labor	
	(10) Other: <i>Construction Contingency</i>	\$27,950.40
	(11) Sub-Total Construction Contract	\$329,666.80
C. Miscellaneous Project Costs		
	(12) Building Purchase	
	(13) & (14) Fixed Equipment Purchase/Lease + Movable Equipment Purchase/Lease	\$384,690.00
	(14a) Information Technology	\$1,650.00
	(15) Furniture	
	(16) Landscaping	
	(17) Consultant Fees (CON Consultant)	
	Architect & Engineering Fees (+ Reimbursables)	\$1,500.00
	Other:	
	Sub-Total Consultant Fees	
	(18) Financing Costs (Bond, Loan, etc.)/Imputed Interest	
	(19) Removal of Existing Equipment	\$3,000.00
	(20) Other (Specify): <i>Nurse Call</i>	\$5,000.00
	<i>Signage</i>	\$1,500.00
	<i>FF&E Contingency</i>	\$38,619.00
	(21) Sub-Total Miscellaneous	\$435,959.00
D. Total Capital Cost of Project	(22) Total Capital Cost of Project -Sum above Subtotals for Rows (11) & (21)	\$765,625.80

*Total construction contract which includes materials and labor.

**ATTACHMENT C –
NC Equipment Comparison Form**

Equipment Comparison Form

NHFMC X-Ray Equipment in Surgery Dept.	Existing Equipment	Replacement Equipment
Type of Equipment (List Each Component)	Urology X-Ray Equipment	Urology X-ray Equipment
Manufacturer of Equipment	GE	Siemens
Tesla Rating for MRIs	N/A	N/A
Model Number	Uroview 2800	Uroskop Omnia Max
Serial Number	P4-0120-L	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	June 2002	TBD
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	~ \$500,000 *	\$765,625.80
Total Cost of Equipment	\$231,786	\$368,465
Fair Market Value of Equipment	\$0	\$368,465
Net Purchase Price of Equipment	\$231,786	\$368,465
Locations Where Operated	Forsyth Medical Center OR	Forsyth Medical Center OR
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	Urologic Procedures	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	Urologic Procedures

Note> * Estimated: Original Costs not available due to age of equipment & system conversions