



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

July 9, 2019

Lisa Griffin
llgriffin@novanthealth.org

Exempt from Review – Replacement Equipment

Record #: 2975
Facility Name: Novant Health Presbyterian Medical Center
FID #: 943501
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Replace existing angiography equipment
County: Mecklenburg

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 25, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(f). Therefore, you may proceed to acquire without a certificate of need the Siemens Artis Q biplane angiography equipment to replace the GE OEC 9900 angiography equipment (serial #E27501M4). 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, Radiation Protection, 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,

Handwritten signature of Julie M. Faenza
Julie M. Faenza
Project Analyst

Handwritten signature of Martha J. Frisone
Martha J. Frisone
Chief

cc: Construction Section, DHSR
Radiation Protection Section, DHSR
Acute and Home Care Licensure and Certification 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
www.ncdhhs.gov/dhsr • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Faenza, Julie M

From: Faenza, Julie M
Sent: Wednesday, July 3, 2019 1:16 PM
To: 'Griffin, Lisa L (CON)'
Subject: RE: [External] RE: [PMC IR2 REER Letter to Agency.pdf]

Thanks!

Julie M. Faenza, Esq.

Project Analyst, Certificate of Need
Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section
North Carolina Department of Health and Human Services

919 855 3873 office
Julie.Faenza@dhhs.nc.gov

From: Griffin, Lisa L (CON) <lgriffin@novanthealth.org>
Sent: Wednesday, July 3, 2019 12:53 PM
To: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>
Subject: [External] RE: [PMC IR2 REER Letter to Agency.pdf]

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

Julie,

Saad Ehtisham is the President & Chief Operating Officer of Novant Health Presbyterian Medical Center (PMC). In this role he has administrative and financial control and oversight of PMC. His office is located in Administration on the First Floor of PMC and is not far from the Radiology Department where this equipment is located. He also documented that the existing equipment is in use in Attachment D of the original letter.

Let me know if you have questions or need further documentation.

Lisa Griffin
(704) 384 - 3462

From: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>
Sent: Wednesday, July 3, 2019 11:52 AM
To: Griffin, Lisa L (CON) <lgriffin@novanthealth.org>
Subject: RE: [External] PMC IR2 REER Letter to Agency.pdf

WARNING: This email originated from **outside** of Novant Health.
Do not click links or open attachments unless you recognize the sender & are expecting the message.

Lisa,

I need a statement from someone – it can be from you, if appropriate, and it can be via email – which documents that financial and administrative control of the entire licensed health service facility is exercised at the site where the equipment proposed to be replaced is currently located.

If you have any questions, please let me know. Thanks!

Julie M. Faenza, Esq.

Project Analyst, Certificate of Need
Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section
North Carolina Department of Health and Human Services

919 855 3873 office
Julie.Faenza@dhhs.nc.gov

From: Griffin, Lisa L (CON) <lgriffin@novanthealth.org>
Sent: Wednesday, June 26, 2019 2:23 PM
To: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>
Cc: Flores, Disraeliza <Disraeliza.Flores@dhhs.nc.gov>
Subject: [External] PMC IR2 REER Letter to Agency.pdf

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

Julie,

Please find attached a replacement equipment exemption notice for angiography equipment at NH Presbyterian Medical Center.

Call me with any questions or if you need additional information.

Thank you,

Lisa Griffin

Manager Planning
Novant Health
Phone: (704) 384 - 3462

----- This message and any included attachments are from NOVANT HEALTH INC. and are intended only for the addressee(s). The information contained herein may include trade secrets or privileged or otherwise confidential information. Unauthorized review, forwarding, printing, copying, distributing, or using such information is strictly prohibited and may be unlawful. If you received this message in error, or have reason to believe you are not authorized to receive it, please promptly delete this message and notify the sender by email. If you believe that any information contained in this message is disparaging or harassing or if you find it objectionable please contact Novant Health, Inc. at 1-844-266-8268 or forward the email to reports@novanthealth.org. Thank you.

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.

----- This message and any included attachments are from NOVANT HEALTH INC. and are intended only for the addressee(s). The information contained herein may include trade secrets or privileged or otherwise confidential information. Unauthorized review, forwarding, printing, copying, distributing, or using such

information is strictly prohibited and may be unlawful. If you received this message in error, or have reason to believe you are not authorized to receive it, please promptly delete this message and notify the sender by email. If you believe that any information contained in this message is disparaging or harassing or if you find it objectionable please contact Novant Health, Inc. at 1-844-266-8268 or forward the email to reports@novanthealth.org. Thank you.

June 25, 2019

Via Email

Julie Faenza, 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 Presbyterian Medical Center
Replacement of Angiography Bi-Plane Equipment.
Charlotte, North Carolina (FID # 943501; Mecklenburg County)

Dear Ms. Faenza:

Novant Health Presbyterian Medical Center (NHPMC) intends to replace an existing angiography bi-plane located in the Radiology Department at the hospital in Charlotte, North Carolina pursuant to N.C. Gen. Stat. 131E-184(f). The existing angiography equipment is seven years old and in need of technological upgrading and expanded capabilities. Therefore, NHPMC will acquire a new Siemens Artis Q Neurorad system. See **Attachment A** for the Equipment. Also note that the equipment quote expires on September 30, 2019. As part of the equipment cost, the vendor will provide onsite clinical training for the equipment. The existing equipment will be removed by the vendor and not used within North Carolina without appropriate CON notice. The total capital cost for the proposed replacement equipment project is estimated to be \$2,272,412¹. See **Attachment B** – Project Capital Cost.

NHPMC's project meets the requirements set forth in N.C. Gen. Stat. 131E-184(f) for "replacement equipment" that exceeds two million (\$2,000,000) threshold in the following ways:

Main Campus:

The existing and replacement angiography bi-plane equipment are and will be located in the Interventional Radiology (IR) Department at the Novant Health Presbyterian Medical Center, which is located at 200 Hawthorne Lane, Charlotte, North Carolina, 28204. See **Attachment C** for documentation. The existing equipment is still in service per the letter documenting this in **Attachment D**.

Previous Certificate of Need:

The existing angiography equipment was acquired through a replacement equipment exemption in 2012 for a total costs of \$1,290,882. **Attachment E** has the Agency letter deeming the replacement exempt from CON review.

Replacement Equipment:

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

RESEARCH & COMMUNICATIONS
DIVISION OF THE
BUREAU OF ECONOMIC ANALYSIS
MAY 1954

- (1) NHPMC will replace the existing Angiography equipment with the proposed equipment 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 equipment will not be used to provide a new health service.
- (3) The acquisition of the proposed equipment 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.

In support of our request, please find attached:

- Attachment A** – Vendor Equipment Quote
- Attachment B** – Project Capital Costs
- Attachment C** – Main Campus Map
- Attachment D** - In Use Documentation
- Attachment E**- 2012 Replacement Exemption Notice
- Attachment F** – Equipment Comparison Form

NHPMC's acquisition of the replacement equipment 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 \$2,272,412. 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 NHPMC's replacement equipment exemption 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 at (704) 384 - 3462.

Sincerely,



Lisa Griffin
Manager, Operational Planning
Novant Health, Inc.

Enclosures

ATTACHMENT A

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



SIEMENS REPRESENTATIVE
Stuart Wadley - (919) 605-9227

PRELIMINARY PROPOSAL

Customer Number: 0000009163

Date: 5/28/2019

PRESBYTERIAN HOSPITAL
200 HAWTHORNE LN
CHARLOTTE, NC 28204

Quote expires 9/30/2019

Quote Nr: 1-OF0G6U Rev. 1

Artis Q biplane

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

Qty	Part No.	Item Description	Extended Price
1	14434122	<p>Artis Q biplane Neurorad. Artis Q biplane for interventional neuroradiology The Artis Q product line is setting new standards in Interventional Imaging.</p> <p>The Artis Q biplane for interventional neuroradiology 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 GIGALIX X-ray tube concentrates high pulse power on small, square-shaped focal spots (flat emitter technology for all focal spots). This provides unprecedented image quality for confidence in challenging situations.</p> <p>Imaging two projections simultaneously saves time and contrast. With the floor or ceiling-mounted stand full patient coverage is achievable.</p> <p>The patient table is fitted with a freely movable patient positioning tabletop.</p> <p>The as40HDR and as20 flat detectors are optimized for radiology and allow for steep angulations.</p> <p>Digital acquisition technology and digital subtraction angiography with up to 7.5 f/s in 1k/12 bit matrix are available.</p> <p>The complete CARE+CLEAR package offers optimal image quality at the lowest reasonable dose.</p> <p>Live and reference images are displayed on four 19" flat screens in the exam room. In the control room live images are displayed on two additional screens.</p>	\$1,055,812

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



SIEMENS REPRESENTATIVE
 Stuart Waddey - (919) 605-9227

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description	Extended Price
1	14434150	FD as40HDR (B) ANGIO/SUR ins as20 Enlarging your field of view When ordering this flat detector, the following components of the basic configuration - as20 flat detector - Cardiac collimator in plane B has been replaced by - as40HDR flat detector - Anglo collimator	\$24,120
1	14432949	MULTISPACE.F Manual stand rotation for additional work positions.	\$2,325
1	14432948	Automap Automatic stand positioning depending on the selected reference image and automatic reference image selection depending on the stand positioning.	\$1,175
1	14434153	8P wireless footswitch ins. of cbl For release of fluoroscopy, exposure and table brake, roadmap selection and mask reset as well as a configurable additional function. Note: This 8-pedal wireless footswitch replaces the 4-pedal or 8-pedal wired footswitch described in the basic configuration.	\$3,214
1	14432896	Prep. for PERISTEPPING/-VISION Motorized stepping of the patient table in the longitudinal direction for peripheral examinations.	\$3,400
1	14432903	wide TT thin mat. ins. of std. TT Patient positioning tabletop made of carbon fiber in wide, straight design for interventional, radiological examinations. The tabletop is straight all the way to the head area. Matching the wide patient positioning tabletop, special-foam mattress, 4 cm, made of open-pore polyurethane material and a latex-free cover. Note: The wide patient positioning tabletop with the thin mattress replaces the narrow tabletop, including mattress, described in the basic configuration. The head-end holder, handles, and shoulder supports are eliminated because they can only be used with the narrow tabletop.	\$0
1	14432894	Laser crosshairs Laser crosshairs integrated in the cover of the flat detector and tableside operation for easier, quicker and dose-saving positioning of the patient (with biplane systems only plane A).	\$3,717
1	14434160	Fluoro Loop Storage and display of dynamic fluoroscopic sequences (Fluoro Loop), for both planes. 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.	\$16,321
1	14432925	PERISTEPPING / PERIVISION Motorized stepping for real-time bolus chasing. C-arm stepping with ARTIS pheno and ceiling mounted systems, table stepping with floor mounted and biplane systems.	\$19,193

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



SIEMENS REPRESENTATIVE
 Stuart Waddey - (919) 605-9227

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description	Extended Price
		Peripheral digital angiography with stepping and online subtraction display.	
1	14432943	Vascular analysis Vessel analysis with determination of degree of stenosis, distance measurement and calibration.	\$4,577
1	14432832	syngo interv. Neuro Engine as40 A dedicated workstation for reconstruction, post-processing and handling of 3D information including specific 2D and 3D applications for interventional neuroradiology. The package includes the following functionalities: 3D high-contrast and CT-like soft-tissue imaging (syngo DynaCT), 3D roadmap for dynamic overlay of planning data and 3D volumes on live images (fluoroscopy or roadmap). In-room control for table-side operation of advanced applications. Expert-I functionality for remote operation of the XWP. Only for PURE systems, the package also includes: 3D Wizard for expert step-by-step guidance in 3D acquisition, Parallel patient processing capabilities, Fusion functionality for integration of pre-interventional 3D datasets also from other modalities into the Angio-room. Marking of points or lines on the 3D geometry or MPRs and overlay of these markings on live images (e.g. fluoroscopy).	\$67,454
1	14434185	syngo DynaCT Micro Enables unique detail resolution (+40%) in interventional 3D imaging by using all detector pixels in a 22 cm image size with reduced dose. As a result, the smallest structures such as Cochlear implants or stents can be displayed in the best possible manner.	\$5,479
1	14446025	syngo DynaCT SMART Streak Metal Artifact Reduction Technique for syngo DynaCT images. Metal implants, like coils and stent markers, create artifacts in the reconstructed images that might make it difficult to detect bleedings or restenosis around the ends of the stent, for instance. syngo DynaCT SMART is a dedicated reconstruction algorithm to reduce metal artefacts. This type of integrated image reconstruction protocol results in 3D volumes with reduced metal artefacts.	\$22,795
1	14446029	syngo NeedleGuidance A software module for planning and control of needle procedures. The application enables the planning of one or multiple needle paths based on intraoperative syngo DynaCT images, or a preoperative 3D volume of a CT, PET/CT or MR system, in combination with Fusion functionality. Optimal progression views for easy control during needle insertion are calculated and suggested by the system and the planned needle path is overlaid on the live 2D image for easy guidance. Interventions such as vertebroplasties, kyphoplasties, pedicle screwing, biopsies, drainages and ablations can be performed on the angiography system with greater confidence.	\$11,398
1	14432961	syngo Embolization Guidance syngo Embolization Guidance is an application for planning and performing embolizations. For Application Software VD2 the easy one-click syngo Embolization Guidance application automatically detects and highlights tumor-feeding vessels for targeted embolization of the liver - supporting complete tumor embolization, which is important for an effective and safe treatment.	\$6,849
		Disclaimer for Application Software VD2: The products/features here mentioned are not commercially available in all countries. Due to regulatory reasons their future availability cannot be guaranteed. Please contact your local Siemens organization for further details.	
1	14432970	syngo Angio Package Software package consisting of DSA Angio Viewer as well as High-Speed Review for real-time	\$8,219

Siemens Medical Solutions USA, Inc. Confidential

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



SIEMENS REPRESENTATIVE
 Stuart Waddey - (919) 605-9227

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description	Extended Price
		display (with the same frame rate as the acquisition) of native and subtracted angiography images.	
2	14432953	<p>Lower body radiation protection</p> <p>This radiation shield protects the user from scattered radiation when standing at the table side. It can be attached to the accessory rails either on the right or on the left side of the patient positioning table.</p> <p>It provides the user an additional accessory rail.</p> <p>It includes a basic unit (71.5 cm x 75 cm / 28.2" x 29.5" (l x w); 7.7 kg / 16.98 lb), one lower body radiation protection pivot swivel element (77 cm x 48 cm / 30.3" x 18.9" (l x w); 3.8 kg / 8.4 lb) and three clip-on units (57 cm / 22.4" x 33 cm / 12.99" (l x h), 2.2 kg / 4.85 lb; 27 cm / 10.6" x 33cm / 12.99", 0.9 kg / 1.98 lb and 27 cm / 10.6" x 25cm / 9.8", 1 kg / 2.2 lb) with a lead of 0.5 mm / 0.02" Pb.</p> <p>The maximum weight of the accessory rails is 40 kg (88.2 lb).</p> <p>Intended only for use with Artis / ARTIS tables.</p>	\$8,364
1	14434157	<p>Moveable upper body rad. protection</p> <p>This radiation shield protects the user from scattered radiation. For room heights up to 290 cm / 114.2".</p> <p>It includes a ceiling rail (4 m / 157.5"), a ceiling mounted and movable stand (80 cm or 57 cm / 31.5" or 22.4"), a support arm (75 cm x 90 cm / 29.5" x 35.4") and an acrylic glass.</p> <p>The shield is made of acrylic glass with lead equivalent of 0.5 mm (w x h: 61 cm x 76 cm / 24" x 29.9"), which can pivot and rotate around a fixed point with a range of 360 degrees.</p> <p>The operation range is limited when used with Artis floor/biplane MN. Max. weight: 18 kg / 39.68 lb.</p>	\$6,285
1	14440512	<p>LED Exam Light</p> <p>Ceiling-mounted, flexible positionable examination light with focusable light system. It is fully integrated into the ceiling-installed radiation protection mounting unit.</p> <ul style="list-style-type: none"> - Luminance: 60,000 Lux for 100 cm / 39.4" distance - Working distance: 70 to 140 cm / 27.6" to 55.1" - Color rendering index Ra at 4500 Kelvin: 95 - Color temperature: 4,300 Kelvin - Focusable light field: 14 to 25 cm / 5.5" to 9.8" - Diameter of light head: 33 cm / 13" - Number of LEDs: 19 - Total input power: 20 VA 	\$5,015
1	14440411	<p>Intercom - Comfort</p> <p>Intercom system for communication between examination room and control room.</p> <p>It includes</p> <ul style="list-style-type: none"> - a microphone with a control box for the control room - a microphone with an adaptive acoustic filter for background noise suppression for the examination room - a footswitch for conversation selection for the examination room <p>The microphone of the examination room is installed on the ceiling.</p>	\$821

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



SIEMENS REPRESENTATIVE
 Stuart Wadley - (919) 605-9227

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description	Extended Price
1	14443011	<p>Large Display dlagn. Protection</p> <p>The high quality laminated glass protective screen protects the panel of the monitor against mechanical damage and fluid ingress on the front. It is suited for clinical image evaluation.</p> <p>Features: The laminated glass enforces high mechanical strenght and resistivity against mechanical impact, the special coating reduces reflections for a continuous image quality, excellent spectral transmisison of at least 98%, can be added to existing Artis Large Display Installations. Weight: approx. 12kg (55") up to 16kg (60")</p> <p>Note: Observe the maximum permissible load of the display suspension, a combination with other options mounted to the display suspension might be restricted.</p>	\$4,750
1	14440497	<p>Long tabletop with thin mattress</p> <p>This tabletop has an extended length of 2637 ± 1 mm / 103.8 ± 0.04". It includes a carbon fiber patient tabletop and a set of three Velcro body straps for securing and compressing the patient. Maximum weight: 200 kg / 440.9 lb. Weigth: 19 kg / 41.9 lb. Width: 525 ± 0.5 mm / 20.7 ± 0.2". Matching this tabletop a mattress and a mattress cover is included. This mattress adapts to the individual body shape under the influence of body weight and heat. It is made of open-pore polyurethane material and a mattress cover. Mattress thickness: 40 ± 5 mm (1.6 ± 0.2"). Mattress weight: 5 kg (11 lb).</p>	\$9,491
1	14434205	<p>Secondary operation on table</p> <p>Second control at tableside.</p>	\$314
1	14434207	<p>Device secondary operation</p> <p>Additional control module, monoplane, for all functions of the C-arm movements and multileaf collimator. For both acquisition planes for a biplane system.</p>	\$3,620
1	14434208	<p>Table secondary operation</p> <p>Second control module to remote-control the patient table in the examination room. Table control within the degrees of freedom supported by the motor drive.</p> <p>Release knob in connection with the standard table for the table with stepping. Joystick in connection with the operating table or the table with tilting.</p>	\$1,018
1	14434231	<p>Sec. operation in the control room</p> <p>Interface for connecting the additional system control from the control room.</p> <p>Rail profile for hanging control modules (e.g. the table module) in the control room.</p> <p>Safety button for switching off all system functions from the control room.</p>	\$3,114
1	14440510	<p>Secondary Hand Switch Ctrl (C Room)</p> <p>Additional hand switch for radiation release and additional control functions.</p>	\$585

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



SIEMENS REPRESENTATIVE
 Stuart Waddey - (919) 605-9227

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description	Extended Price
1	14432950	DICOM RIS-Modality Worklist Import of patient/examination data from an external RIS/HIS patient management system with DICOM MWL (Modality Worklist).	\$698
1	14434232	Injector conn. in the control room Interface for controlling the contrast medium injector in the control room. Injectors can be offered by Siemens Healthcare Accessory Solutions	\$2,574
1	14434172	Large Display Preparation for the large color flat screen display on a ceiling-mounted, longitudinally mobile, swiveling, rotating, and height-adjustable display holder in the examination room. Note: If a Large Display is selected, the Artis basic configuration includes a connection kit for the Large Display instead of the displays for the examination room. The type of large display can be chosen with a separate position.	\$47,414
1	14434176	Large Display video controller 18 Large Display Video Controller 18 is the middle of three different video controller sizes. A maximum of 18 video signals can be connected and displayed simultaneously on the Large Display. The Large Display video controller 18 receives various internal and external video signals for presentation to scale on the Large Display. Up to 18 external and internal video sources can be connected (max. 14 DVI-D and 4 analog (VGA) channels).	\$27,354
1	14440573	Add 19" display for LD (rear mount) 19" TFT display including 36 m cable with DVI-D connection and transceiver for display installation on the rear of the DCS in combination with the Large Display.	\$4,513
1	14443012	LD High Contrast panel size 55" Large color flat screen display (including cables) for the examination room, with a panel diagonal of 55". This large display version provides an excellent clinical image quality due to its new IPS panel technology.	\$0
1	AXA_INITIAL_3 2	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.	\$7,800
1	AXA_FOLLOW UP_32	Follow-up training 32 hrs Up to (32) 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.	\$7,800
1	AXA_FOLLOW UP_12	Follow-up training 12 hrs Up to (12) 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	\$4,200

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



SIEMENS REPRESENTATIVE
 Stuart Waddey - (919) 605-9227

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description	Extended Price
1	AXA_FOLLOW UP_12	obligation to provide the training will expire without refund. Follow-up training 12 hrs Up to (12) 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.	\$4,200
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.	\$450
1	AXA_PURE_E SSCL	AX Artis PURE Essential Class Tuition for (1) Imaging professional to attend Siemens class at Siemens Training Center. The Artis PURE Essentials Course is a 3.5-day classroom course beginning on Tuesday at 8:30 a.m. and ending on Friday at 12:00 p.m. It is designed to provide the participant with an in-depth knowledge of the essential functions of the Artis system as well as the skills needed to perform these functions. Through the use of demonstrations, lectures, and hands-on lab experience using an Artis system, participants will learn Artis system principles and workflows of patient examinations. Additionally, participants have the opportunity to meet other users and share their experiences and solutions to various challenges of the IR, cath lab, and the Hybrid OR environment. This class includes lunch, economy airfare, and lodging for (1) imaging professional. All arrangements must be arranged through Siemens designated travel agency. This educational offering must be completed by the later of (12) months from purchase or install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.	\$4,500
1	AXA_PURE_3D ADVCL	AX PURE 3D Advanced Class Tuition for (1) imaging professional to attend Siemens class at Siemens Training Center. The Advanced PURE Applications classroom course is a 4 day classroom course beginning on Tuesday at 8:30 a.m. and ending on Friday at 4:30 p.m. This course will provide the participants with the in-depth knowledge of the essential functions of the PURE advanced 3D applications software as well as the skills needed to perform these functions. Through the use of demonstrations, lectures, and hands-on lab time on a PURE system, participants will learn the advanced post-processing techniques and advanced 3D applications for PURE software. This class includes lunch, economy airfare, and lodging for (1) imaging professional. All arrangements must be arranged through Siemens designated travel agency. This educational offering must be completed by the later of (12) months from purchase or install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.	\$4,500
1	AXA_PURE_3D ADVCL	AX PURE 3D Advanced Class Tuition for (1) Imaging professional to attend Siemens class at Siemens Training Center. The Advanced PURE Applications classroom course is a 4 day classroom course beginning on Tuesday at 8:30 a.m. and ending on Friday at 4:30 p.m. This course will provide the participants with the in-depth knowledge of the essential functions of the PURE advanced 3D applications software as well as the skills needed to perform these functions. Through the use of demonstrations, lectures, and hands-on lab time on a PURE system, participants will learn the advanced post-processing techniques and advanced 3D applications for PURE software. This class includes lunch, economy airfare, and lodging for (1) imaging professional. All arrangements must be arranged through Siemens designated travel agency. This educational offering must be completed by the later of (12) months from purchase or install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.	\$4,500

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



SIEMENS REPRESENTATIVE
 Stuart Waddey - (919) 605-9227

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description	Extended Price
1	AXA_PURE_E SSCL	AX Artis PURE Essential Class Tuition for (1) imaging professional to attend Siemens class at Siemens Training Center. The Artis PURE Essentials Course is a 3.5-day classroom course beginning on Tuesday at 8:30 a.m. and ending on Friday at 12:00 p.m. It is designed to provide the participant with an in-depth knowledge of the essential functions of the Artis system as well as the skills needed to perform these functions. Through the use of demonstrations, lectures, and hands-on lab experience using an Artis system, participants will learn Artis system principles and workflows of patient examinations. Additionally, participants have the opportunity to meet other users and share their experiences and solutions to various challenges of the IR, cath lab, and the Hybrid OR environment. This class includes lunch, economy airfare, and lodging for (1) imaging professional. All arrangements must be arranged through Siemens designated travel agency. This educational offering must be completed by the later of (12) months from purchase or install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.	\$4,500
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.	\$7,800
1	E93PM150UAX	Eaton 93PM-150 kW UPS Complete system backup without interruption. One UPS per lab. Includes the following: Eaton 93PM UPS Electronics Cabinet w/integrated maintenance bypass sidecar Eaton 93PM Single Battery Cabinet System (Full load back-up time @ 150kW of 7.1 minutes.) Eaton 93PM Remote Monitoring Panel Network Card Eaton 24x7 start-up One year (24x7) warranty through Eaton Corp. Not approved for sites that require OSHPD. Shipment is to customer's dock. Customer is responsible for logistics from the dock to inside location.	\$56,909
2	GEL104013660 1278	Black anti-fatigue mat 36x60 Black NewLife EcoPro anti-fatigue mat (36 inches x 60 inches), 3/4 inch polyurethane foam, fluid and dirt resistant with anti-microbial properties, matte textured surface. The ultimate employee benefit for workers who stand, are ergonomically designed to provide the perfect balance of premium comfort and optimal support. Proprietary Cellulon(r)Polyurethane Technology stands up to the tough demands of commercial environments while providing lasting comfort that won't bottom out over time. This eco-friendly line of anti-fatigue mats is certified by the National Floor Safety Institute for its high traction bottom surface.	\$400
1	QFIX8002505	Qfix DSA-3Q HEAD HOLDER The Qfix DSA-3Q Head Holder is designed for neurological procedures which require head immobilization and multi-positioning, such as angiography. The DSA-3Q universal mounting clamp securely attaches to the head end of flat-top tables ranging from 0.50" (1.3cm) to 1.75" (4.5cm) in thickness. The composite skull cradle provides rigid positioning. Easy-to-manuever	\$3,143

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



SIEMENS REPRESENTATIVE
 Stuart Waddey - (919) 605-9227

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description	Extended Price
		swivel joint allows for various head positions and enables quick positioning changes. Includes two hook and loop straps for securing the forehead and chin and a foam pad insert for patient comfort.	
1	AXA_RIG_QBP _STD	Standard Rigging Q Q.Zen BP	\$17,500
1	AXA_BUDG_A DDL_RIG	Budgetary Add'l/Out of Scope Rigging \$12,000	\$12,000
1	QFIX8002505	Qfix DSA-3Q HEAD HOLDER The Qfix DSA-3Q Head Holder is designed for neurological procedures which require head immobilization and multi-positioning, such as angiography. The DSA-3Q universal mounting clamp securely attaches to the head end of flat-top tables ranging from 0.50" (1.3cm) to 1.75" (4.5cm) in thickness. The composite skull cradle provides rigid positioning. Easy-to-manuever swivel joint allows for various head positions and enables quick positioning changes. Includes two hook and loop straps for securing the forehead and chin and a foam pad insert for patient comfort.	\$3,143
System Total:			\$1,525,324 ①

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



SIEMENS REPRESENTATIVE
 Stuart Waddey - (919) 605-9227

PRELIMINARY PROPOSAL

OPTIONS on Quote Nr: 1-OF0G6U Rev. 1

OPTIONS for Artis Q biplane

All items listed below are OPTIONS:

Qty	Part No.	Item Description	Extended Price
1	14440447	<p>Acc. rail module, wide tabletop</p> <p>This is an attachable module with accessory rails for placing the control modules near the patient's abdomen.</p> <p>It includes a carbon fiber module with accessory rails (45 cm / 17.7") attached to the right and left slides over the outer edges of the patient positioning tabletop.</p> <p>Length: 48 cm (18.9 ")</p> <p>Width (without accessory rails): 47.5 cm (18.7") 55 cm / 21.65"</p> <p>Width (with accessory rails): 54.5 cm (21.5") 62 cm / 24.4"</p> <p>Length: 62 cm (24.4")</p> <p>Weight: 5.9 kg (13 lb)</p> <p>Maximum weight: 40 kg (88.19 lb).</p> <p>Intended only for use with Artis / ARTIS wide tabletop.</p>	+ \$3,245 ①
1	14434130	<p>Emer. pwr. supply img. system bipl.</p> <p>Emergency power supply for the biplane imaging system</p> <p>Bridging of the imaging system power supply (50/60 Hz) until line voltage is back to prevent loss of data. In case of power failures of more than 90 seconds the imaging system will be shut down automatically.</p> <p>Nominal power: 2.2 kW</p>	+ \$2,869 ①

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



SIEMENS REPRESENTATIVE
 Stuart Waddey - (919) 605-9227

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description	Extended Price
1	BART700PEDL	<p>Mark 7 Arterion, Pedestal System</p> <p>The Arterion Mark 7 Pedestal contrast medium injector can be positioned anywhere at the patient positioning table on a mobile unit, for direct operation of all functions in the examination room.</p> <p>The injector system includes: A mobile pedestal stand with electronics unit, a contrast medium heater and a connection cable to the manual release. A support arm with injector head and a control lever for moving the injector head. A user control console with large touch screen and corresponding additional monitoring display on the injector head.</p> <p>Functions Pressure limitation: for 150 ml syringes 689 to 8273 kPa, corresponds to 100 to 1200 psl. .</p> <p>Flow rates for 150 ml syringes: 0.1 to 45 ml/s in increments of 0.1 ml/s 0.1 to 59.9 ml/min in increments of 0.1 ml/min rise/fall: 0 to 9.9 s in increments of 0.1 seconds</p> <p>Release delay for injection or radiation: 0 to 99.9 s in increments of 0.1 s.</p> <p>Adjustable volume for 150 ml syringes: 1 ml to the max. syringe capacity in increments of 1 ml.</p> <p>Fill rate: Variable syringe filling speed 1-20ml/s.</p> <p>Injection protocols: Up to 40 injection protocols possible.</p> <p>Parameters currently displayed on the touch screen display and on the head display: Injection speed Injection volume Remaining volume Injection duration Applied pressure</p> <p>Contrast medium heating: Nominal 35°C (95°F)+-5°C (9°F)</p> <p>Injection data memory Up to 50 Injection data items stored</p> <p>Included in the scope of delivery Injector standard configuration 150 ml SIEMENS interface cable Operator Manual</p>	+ \$27,067 ①

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



SIEMENS REPRESENTATIVE
Stuart Wadley - (919) 605-9227

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description	Extended Price
		Service manual (English).	
		Power supply 200 V to 250 V; 50/60 Hz.	
1	BINSART700P	Arterion Pedestal Install	+ \$1,545 ^①

FINANCING: The equipment listed above may be financed through Siemens. Ask us about our full range of financial products that can be tailored to meet your business and cash flow requirements. For further information, please contact your local Sales Representative.

Siemens Healthcare is pleased to submit this Preliminary Pricing Proposal. A Preliminary Pricing Proposal is provided for planning purposes only; it is not contractually binding. To receive a contractually binding proposal for the Products listed above, inclusive of Terms, Conditions, and Warranty coverage, please contact your Siemens Healthcare Sales Representative.

Siemens Healthcare

Stuart Wadley
(919) 605-9227
stuart.wadley@siemens-
healthineers.com

$\Sigma \textcircled{1} = \$ \underline{\underline{1,560,060}}$

ATTACHMENT B

**Projected Capital Cost Form
PMC Angiography Equipment - IR Room 2**

Building Purchase Price	
Purchase Price of Land	
Closing Costs	
Site Preparation	
Construction/Renovation Contract(s)	\$ 405,083
Landscaping	
Architect / Engineering Fees	
Medical Equipment	\$ 1,560,050
Non-Medical Equipment	\$ 262,279
Furniture	
Consultant Fees (Engineering Fees)	\$ 45,000
Financing Costs	
Interest during Construction	
Other (specify)	
Total Capital Cost	\$ 2,272,412



CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

I certify that, to the best of my knowledge, the projected capital cost for the proposed project is complete and correct.

Date Signed: 6/12/19

Signature of Licensed Architect or Engineer

CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT

I certify that, to the best of my knowledge, the projected total capital cost for the proposed project is complete and correct and that is our intent to carry out the proposed project as described.

Date Signed: 6/17/19

Signature of Officer/Agent

President

Title of Officer/Agent

ATTACHMENT C

ATTACHMENT D



Presbyterian Medical Center

200 Hawthorne Lane
Charlotte, NC 28204

June 11, 2019

Julie Faenza, Project Analyst, Certificate of Need
North Carolina Department of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Novant Health Presbyterian Medical Center
Documentation of Existing Angiography Equipment Still in Use

Dear Ms. Faenza:

This letter serves as documentation that the existing angiography equipment (GE OEC 9900) is still in use in the Interventional Radiology Department located at Novant Health Presbyterian Medical Center. We propose to replace it with new angiography equipment in 2019.

Please let me know if you have questions or need more information.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Saad Ehtisham'.

Saad Ehtisham, FACHE
President & Chief Operating Officer

ATTACHMENT E



North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section

2704 Mail Service Center • Raleigh, North Carolina 27699-2704
<http://www.ncdhhs.gov/dhsr/>

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor
Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief
Phone: (919) 855-3873
Fax: (919) 733-8139

June 27, 2012

Lisa Griffin
Manager, Certificate of Need
Financial Planning and Analysis
Novant Health, Inc.
2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

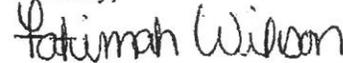
RE: Exempt from Review –Replacement Angiography Equipment / Presbyterian Hospital / Replace
an existing angiography unit in Angiography Room #2 / Mecklenburg County
FID # 943501

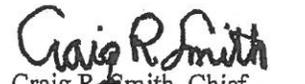
Dear Ms. Griffin:

In response to your letter of June 8, 2012 the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the OEC 9900 Elite angiography unit to replace the existing ADVANTX LCA angiography unit, serial number 34477VPO in Angiography Room #2. Presbyterian Hospital will not be increasing the number of angiography units in the Mecklenburg County angiography inventory nor will Presbyterian Hospital be concurrently operating both angiography units. This determination is based on your representations that the existing angiography unit will be removed by GE Healthcare. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the. In addition, you should contact the Construction Section to determine if they have any requirements for development of the proposed project.

It should be noted that this 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 Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,


Fatimah Wilson
Project Analyst


Craig R. Smith, Chief
Certificate of Need Section

cc: Construction Section, DHSR
Medical Facilities Planning Section, DHSR



Location: 809 Ruggles Drive, Dorothea Dix Hospital Campus, Raleigh, N.C. 27603
An Equal Opportunity/ Affirmative Action Employer



ATTACHMENT F

EQUIPMENT COMPARISON

PMC Angiography Equipment – IR Room #2	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)	Angiography	Angiography
Manufacturer	GE	Siemens
Model number	OEC 9900	Artis Q
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	E27501M4	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	October 2012	TBD
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	\$2,272,412
Total cost of the equipment	\$1,290,882	\$1,560,060
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	Interventional Radiology Rm 2	Interventional Radiology Rm 2
Document that the existing equipment is currently in use	(1)	NA
Will the replacement equipment result in any increase in the average charge per procedure?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	N/A
Will the replacement equipment result in any increase in the average operating expense per procedure?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	N/a
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	Interventional Radiology Procs	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	Interventional Radiology Procedures

(1) See enclosed letter documenting that existing equipment is in use

Date of last revision: 5/17/19

