



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 13, 2021

Jacob Rodman, Chief Executive Officer
dlegarth@nc.rr.com

No Review

Record #: 3608
Date of Request: July 6, 2021
Business Name: Raleigh Neurological Clinic, Inc.
Business #: 3406
Project Description: Acquire a Siemens Artis Q biplane system for interventional neuroradiology to be located in a physician office building in Raleigh
County: Wake

Dear Mr. Rodman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request**, the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

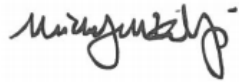
LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Mr. Rodman
July 13, 2021
Page 2

Please do not hesitate to contact this office if you have any questions.

Sincerely,



Michael J. McKillip
Project Analyst



Micheala Mitchell
Section Chief, Healthcare Planning and Certificate of Need

cc: Acute and Home Care Licensure and Certification Section, DHSR
Radiation Protection Section, DHSR

**RALEIGH
NEUROSURGICAL
CLINIC INC**

Intracranial Surgery
Minimally Invasive &
Reconstructive Spine Surgery
Peripheral Nerve Surgery
Cerebrovascular Surgery

**Excellence in Neurosurgery
Since 1954**

5838 Six Forks Road
Raleigh, NC 27609

Phone 919-785-3400
Fax 919-783-7888

Robert Lee Allen, MD
Andrey Belayev, MD
Brandon C. Burnsed, MD
Takanori Fukushima, MD
Lars B. Gardner, DO
Timothy B. Garner, MD
Laith W. Khoury, MD
Russell R. Margraf, MD, PhD
Kenneth J. Rich, MD
Victoria Samuels, MD
William Ashby, PA-C
Sarah Petty Butler, PA-C
Dana Johnson, PA-C
Michelle Mashburn, FNP-C
Ryan Millar, PA-C
Sarah Mouw, PA-C
Ian Perkins, PA-C
Charlotte Spangler, PA-C
Paul Tarangelo, PA-C

July 5, 2021

Mr. Mike McKillip, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

RE: Request for Exemption to Certificate of Need Review for Acquisition of an Artis Q Biplane System / Wake County

Dear Mr. McKillip,

This letter is intended to provide advance notice to the Healthcare Planning and Certificate of Need ("CON") Section that Raleigh Neurosurgical Clinic, Inc. ("RNC") is planning to acquire therapeutic medical equipment, specifically, an Artis Q Biplane System that will be located in its clinical office within an existing medical office building at 5221 Six Forks Road, Suite 100, Raleigh. The total cost of the medical equipment is \$710,918. Additional project costs associated with the acquisition of the medical equipment includes lead backed drywall installation and radiation survey totaling \$10,000. The total project cost is \$720,918.

Under the CON statute, biplane equipment is not specifically subject to CON review unless the cost of acquiring the equipment meets the \$750,000 threshold for "Major Medical Equipment" set forth in N.C.G.S. 131E-176(140). Here the cost of the equipment, including all costs to make the equipment operational, will not exceed \$750,000. Accordingly, RNC requests that the Section issue a written determination confirming that its proposed acquisition of an Artis Q Biplane System to be located in its clinical office within an existing medical office building is not subject to CON review.

If you have any questions or need additional information, please do not hesitate to contact me at (919) 785-3400.

Sincerely,



Jacob Rodman
Chief Executive Officer
Raleigh Neurosurgical Clinic, Inc.

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

SIEMENS REPRESENTATIVE
Stephen Argo - +1 (336) 210-6178
craig.argo@siemens-healthineers.com

PRELIMINARY PROPOSAL

Customer Number: 0000331057

Date: 06/15/2021

RALEIGH NEUROSURGICAL CLINIC, INC.
5838 SIX FORKS RD # 100
Raleigh, NC 27609

Quote Nr. CPQ-385959 Rev. 0

Artis Q biplane eco Neurorad.

All items listed below are included for this system:

Qty	Part No.	Item Description
1	14458097	<p>RS Artix Q biplane Neurorad. Artix Q biplane for interventional neuroradiology The Artix Q product line is setting new standards in interventional imaging.</p> <p>The Artix Q biplane for interventional neuroradiology now features PURE®. 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	14434765	<p>RS ecoline AX System delivery With ecoline, Siemens Healthineers offers a portfolio of systems with certified performance at exceptional value.</p> <p>ecoline systems contain components, which have been in use and are refurbished to a quality level as good as new. All ecoline systems are manufactured following</p>

PRELIMINARY PROPOSAL

externally certified processes according to the relevant standards for medical devices¹, including the global refurbishment standard² where applicable. Thus, every ecoline system receives our Proven Excellence Label.

Siemens Healthineers' ecoline systems provide exceptional value performing and looking like new, configurable to individual customer needs and offered at affordable prices.

¹ ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

² IEC PAS 63077:2016 Good refurbishment practices for medical imaging equipment

1 14442456

RS 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
- Angio collimator

1 14442448

RS MULTISPACE.F

Manual stand rotation for additional work positions.

1 14442460

RS Fluoro Loop

Storage and review of dynamic fluoroscopic sequences for both planes. This saves an additional acquisition and helps to reduce dose. The maximum storable fluoroscopic time is limited by the maximum DICOM file size of 4 Gbyte.

1 14442446

RS Vascular analysis

Vessel analysis with determination of degree of stenosis, distance measurement and calibration.

1 14442608

RS 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.

- 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).

1 14442613

RS syngo Angio Package

PRELIMINARY PROPOSAL

Software package consisting of DSA Angio Viewer as well as High-Speed Review for real-time display (with the same frame rate as the acquisition) of native and subtracted angiography images.

1 14442614

RS syngo Scene Compare w/biplane

Dual monitor support with biplane review functionality for the postprocessing of DSA scans. Both the evaluation of bi-planar scenes in synchronized mode and the comparison of scenes to single images are supported. The dynamic comparison of two scenes is also possible.

1 14442451

RS Lower body radiation protection

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.

It provides the user an additional accessory rail.

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.

The maximum weight of the accessory rails is 40 kg (88.2 lb).

Intended only for use with Artis / ARTIS tables.

1 14442459

RS Moveable upper body rad. protection

This radiation shield protects the user from scattered radiation.

For room heights up to 290 cm / 114.2".

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 (94 cm x 91 cm / 37" x 35.8") and an acrylic glass.

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.

The operation range is limited when used with Artis floor/biplane MN.

Max. weight: 18 kg / 39.68 lb.

1 14442475

RS LED Exam Light

Ceiling-mounted, flexible positionable examination light with focusable light system.

It is fully integrated into the ceiling-installed radiation protection mounting unit.

- Luminance: Min 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: min. 95

- Color temperature: 4,100+-200 Kelvin

- Focusable light field: 14 to 25 cm / 5.5" to 9.8"

- Total input power: Max. 24 VA

1 14448215

RS Large Display diagn. protection

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.

Features:

The laminated glass enforces high mechanical strength and resistivity against mechanical impact,

PRELIMINARY PROPOSAL

the special coating reduces reflections for a continuous image quality, excellent spectral transmission of at least 98%, can be added to existing Artis Large Display installations.
Weight: approx. 12kg (55") up to 16kg (60")

Note: Observe the maximum permissible load of the display suspension, a combination with other options mounted to the display suspension might be restricted.

1 14447698

RS Kyphoplasty arm rest "CARD"

This item can be used when it is required to have the patient in a prone (lying face down) position.

It includes the armrest (width: 53.5 cm / 21.1"; length: 35 cm / 13.8") and two pads (thickness: 3.5 cm / 1.38").

Weight: 5.35 kg / 11.8 lb

Maximum weight: 20 kg / 44.09 lb

Intended only for use with Artis narrow tabletop.

1 14442465

RS Sec. operation in the control room

Interface for connecting the additional system control from the control room.

Rail profile for hanging control modules (e.g. the table module) in the control room.

Safety button for switching off all system functions from the control room.

1 14442474

RS Secondary Hand Switch Ctrl (C Room)

Additional hand switch for radiation release and additional control functions.

1 14442449

RS DICOM RIS-Modality Worklist

Import of patient/examination data from an external RIS/HIS patient management system with DICOM MWL (Modality Worklist).

1 14442616

RS 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

1 14442462

RS 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).

1 14442461

RS 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.

1 14448305

RS LD High Contrast panel size 55"

Large color flat screen display (including cables) for the examination room, with a

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

SIEMENS REPRESENTATIVE
Stephen Argo - +1 (336) 210-6178
craig.argo@siemens-healthineers.com

PRELIMINARY PROPOSAL

panel diagonal of 55". This large display version provides an excellent clinical image quality due to its new IPS panel technology.

1 AXA_RIG_QBP_
STD

Standard Rigging Q Q.Zen BP

2 AXA_ADD_28

Additional onsite training 28 hrs

Up to (28) 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 GEL1040136601
278

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®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.

1 AXA_BUDG_AD
DL_RIG

Budgetary Add'l/Out of Scope Rigging \$5,000

System Total

\$ 710,918.00

PRELIMINARY PROPOSAL

OPTIONS on Quote Nr : CPQ-385959 Rev. 0

OPTIONS for Artis Q biplane eco Neurorad.

All items listed below are OPTIONS and will be included on this system ONLY if initialed: (See Detailed Technical Specifications at end of Proposal.)

Qty	Part No.	Item Description	Extended Price
1	AM0160C	<p>Adept STARSystem Radial positioning equipment intended for clinicians working on the right.</p> <p>Includes STARBoard, leg arm support and STARTable.</p> <p>A key function of the STARBoard is its ability to present the patients wrist in the hyper-extended position whilst access is achieved, then simply return it to a more relaxed, medially-rotated position, for the duration of the procedure, allowing greater patient comfort. Crafted in carbon fiber for superior strength, radiolucency and durability, the STARBoard is light weight and compact.</p> <p>STARSupport connects to the STARBoard after radial access is gained facilitating left arm procedures for superior patient comfort.</p> <p>STARTable not only provides clinicians with an adjustable work surface, the vertical shield reduces X-ray scatter.</p> <p>Includes one year warranty through Adept.</p>	+ \$ 7,367.00
1	BART700TABL	<p>Mark 7 Arterion, Table Mount Injector The Arterion Mark 7 Table contrast medium injector allows for the remote installation of the system power supply and installation of the injector head onto a table bracket.</p> <p>The injector system includes: Power supply and injector head with corresponding cabling An adjustable height table bracket for the injector head A desk mounted user control console with large touch screen</p> <p>Functions Pressure limitation: for 150 ml syringes 689 to 8273 kPa, corresponds to 100 to 1200 psi. .</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:</p>	+ \$ 27,900.00

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

SIEMENS REPRESENTATIVE
Stephen Argo - +1 (336) 210-6178
craig.argo@siemens-healthineers.com

PRELIMINARY PROPOSAL

Variable syringe filling speed 1-20ml/s.

Injection protocols:
Up to 40 injection protocols possible.

Parameters currently displayed on the touch screen display and on the head display:

Injection speed
Injection volume
Remaining volume
Injection duration
Applied pressure

Contrast medium heating:
Nominal 35°C (95°F)+-5°C (9°F)

Injection data memory
Up to 50 injection data items stored

Included in the scope of delivery
Injector standard configuration 150 ml
SIEMENS interface cable
Operator Manual
Service manual (English).

Power supply
200 V to 250 V; 50/60 Hz.

1	BINSART700R	Arterion Rack Mnt Install	+ \$ 2,225.00
---	-------------	----------------------------------	----------------------

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

SIEMENS REPRESENTATIVE
Stephen Argo - +1 (336) 210-6178
craig.argo@siemens-healthineers.com

PRELIMINARY PROPOSAL

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
Stephen Argo
+1 (336) 210-6178
craig.argo@siemens-healthineers.com