



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

VIA EMAIL ONLY

October 26, 2017

Charles Hauser
Piedmont Stone Center

Exempt from Review – Replacement Equipment

Record #: 2425
Facility Name: Piedmont Stone Center
FID #: 060074
Business Name: Piedmont Stone Center, PLLC
Business #: 1420
Project Description: Replace existing mobile lithotripter
County: Forsyth

Dear Mr. Hauser:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of October 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 Modularis Variostar mobile lithotripter to replace the existing Siemens Modularis mobile lithotripter, Serial # 1925. 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,

Celia C. Inman
Project Analyst

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

cc: Adult Care Licensure Section, DHR
Shareta Blackwell, Program Assistant Healthcare Planning, DHR

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





Piedmont Stone Center, PLLC



Clinical Office
(336) 765-6373
Fax (336) 765-6436

PO Box 25866 • Winston Salem, NC 27114-5866

Business Office
(336) 714-1258
(888) 373-6328
Fax (336) 714-2554

October 25, 2017

Martha J. Frisone
Assistant Chief, Healthcare Planning and Certificate of Need Section
Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

Re: Replacement Equipment Exemption Notice

Facility Name: Piedmont Stone Center
FID #: 060074
Business Name: Piedmont Stone Center, PLLC
Business #: 1420
Project Description: Replace existing mobile lithotripter
County: Forsyth

Dear Ms. Frisone:

I am writing to provide the Agency with prior written notice of Piedmont Stone Center's intention to acquire a replacement mobile lithotripter pursuant to N.C. Gen. Stat. § 131 E-184(a)(7). Piedmont Stone Center would like to replace one of its existing lithotripters which was originally purchased in 2006. The total cost for the replacement lithotripter is \$413,952 which includes the lithotripter and sales tax. The tractor and trailer are not being replaced. The following exhibits are attached. **Exhibit A** is an equipment comparison form. **Exhibit B** is the capital cost form. **Exhibit C** is the quote from Siemens, the manufacturer of the lithotripter to be installed in an existing trailer.

This project meets the requirements of N.C. Gen. Stat. § 131E-176(22)a because the equipment costs less than \$2 million and is being purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. The total capital costs for this replacement are \$413,952 and includes all costs essential to acquiring and making the replacement lithotripter operational. The existing lithotripter, which is now fourteen years old, is fully depreciated and has zero fair market value. The existing lithotripter will be disposed of when the replacement arrives.



This project also meets the requirements of 10A NCAC 14C.0303 because the replacement lithotripter is comparable to the existing lithotripter. Specifically:

- (1) The replacement lithotripter has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements;
- (2) The replacement equipment is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
- (3) The acquisition of the equipment does 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.

See 10A NCAC 14.C0303(d)(1-3). None of the exclusions in 10A NCAC 14.C0303(e)(1-5) apply here.

Accordingly, Piedmont Stone Center respectfully requests that the Agency issue its written determination that the proposed replacement equipment acquisition is exempt from CON review. Piedmont Stone Center would like to replace this lithotripter in the next few weeks, and would be grateful for the Agency's prompt consideration of this request.

Thank you for your time and attention. Please let me know if you have any questions.

Sincerely,

Charles H. Hauser
Chief Executive Officer

Enclosures

EQUIPMENT COMPARISON

Type of Equipment (List Each Component)	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	N/A	N/A
Model Number	N/A	N/A
Serial Number	1925	30854
Provider's Method of Identifying Equipment	#8	#18
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	12/21/2006	N/A*
Does Provider Hold Title to Equipment or Have a Capital Lease?	Hold Title	Hold Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	See Attached	See Attached
Total Cost of Equipment	\$430,000	\$389,036
Fair Market Value of Equipment	\$0	\$389,036
Net Purchase Price of Equipment	\$430,000	N/A
Locations Where Operated	NC and VA	NC and VA
Number Days In Use/To Be Used in N.C. Per Year	256	256
Percent of Change in Patient Charges (by Procedure)	0%	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	0%	0%
Type of Procedures Currently Performed on Existing Equipment	ESWL**	ESWL**
Type of Procedures New Equipment is Capable of Performing	N/A	ESWL**

*This question is Not Applicable (N/A) because we do not have the new unit yet.

**ESWL is Extracorporeal Shock Wave Lithotripsy.

PROPOSED CAPITAL COSTS


Project Name: Replacement Lithotripter
 Proponent: Piedmont Stone Center, PLLC

A. Site Costs: N/A Because No Land is Being Purchased or Developed		
(1)	Full purchase price of land.....	\$ _____
(2)	Acres _____ Price per Acre \$ _____	
(3)	Closing costs.....	\$ _____
(4)	Site Inspection and Survey	\$ _____
(5)	Legal fees and subsoil investigation	\$ _____
	Site Preparation Costs	
	Soil Borings.....	\$ _____
	Clearing-Earthwork	\$ _____
	Fine Grade For Slab.....	\$ _____
	Roads-Paving.....	\$ _____
	Concrete Sidewalks	\$ _____
	Water and Sewer.....	\$ _____
	Footing Excavation.....	\$ _____
	Footing Backfill.....	\$ _____
	Termite Treatment.....	\$ _____
	Other (Specify).....	\$ _____
	Sub-Total Site Preparation Costs.....	\$ _____
(6)	Other (Specify).....	\$ _____
(7)	Sub-Total Site Costs.....	\$ _____
B. Construction Contract: N/A Because No Construction is Involved		
(8)	Cost of Materials	
	General Requirements	
	Concrete/Masonry	
	Woods/Doors & Windows/Finishes	
	Thermal & Moisture Protection	
	Equipment/Specialty Items	
	Mechanical/Electrical	
	Other (Specify)	
	Sub-Total Cost of Materials.....	\$ _____
(9)	Cost of Labor.....	\$ _____
(10)	Other (Specify).....	\$ _____
(11)	Sub-Total Construction Contract.....	\$ _____
C. Miscellaneous Project Costs		
(12)	Building Purchase.....	\$ _____
(13)	Fixed Equipment Purchase/Lease.....	\$ _____
(14)	Movable Equipment Purchase/Lease.....	\$ 389,036
(15)	Furniture.....	\$ _____
(16)	Landscaping.....	\$ _____
(17)	Consultant Fees	
	Architect and Engineering Fees.....	\$ _____
	Legal Fees	\$ _____
	Market Analysis	\$ _____
	Other (Specify)	\$ _____
	Sub-Total Consultant Fees	\$ _____
(18)	Financing Costs (e.g. Bond, Loan, etc.).....	\$ _____
(19)	Interest During Construction	\$ _____
(20)	Other (Specify) Sales Tax of 6.75%.....	\$ 24,916
(21)	Sub-Total Miscellaneous	\$ 413,952
(22)	Total Capital Cost of Project (Sum A-C above).....	\$ 413,952

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

 (Signature of Licensed Architect or Engineer)

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


 (Proponent - signature of officer)

CEO
 (Title of officer)



SIEMENS REPRESENTATIVE
Andy Greuling

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

Date: 4/18/2017

Customer Number: 0000009076

PIEDMONT STONE CENTER
3825 FOREST GATE DR
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.

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Contract Total: \$385,422
(total does not include any Optional or Alternate components which may be selected)

Proposal valid until 6/30/2017

Estimated Delivery Date: 9/2017

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

This offer is only valid if firm, non-contingent orders for the following quotes are simultaneously placed with Siemens:
1-IZHBQK
1-IZAZDJ
1-IZHBPW

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

Payment terms are 0/60/40

Delivery will additionally include 2 short leg extensions (Part#5567519)

This Quotation is specific to Piedmont Stone 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.

Accepted and Agreed to by:



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

SIEMENS REPRESENTATIVE
Andy Greuling

Siemens Medical Solutions USA, Inc.

By (sign):
Name: Andy Greuling
Title: Product Sales Executive
Date: 6/13/17

PIEDMONT STONE CENTER

By (sign):
Name: Charles H. Hauser
Title: CEO
Date: 6/13/2017

*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:	1-1ZAZDJ Rev. 1
Terms of Payment:	Note in order Text Terms of payment Free On Board: Shipping Point
Purchasing Agreement:	Not Applicable

MODULARIS

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

Qty	Part No.	Item Description
1	14409782	MODULARIS Uro II The fully motorized and ergonomically designed patient table is suitable for lithotripsy and endourological procedures. It is equipped with a lateral cut-out/insert to accommodate the shockwave head during extracorporeal lithotripsy (ESWL). The table is optimized for use by an operator at several hospitals. It includes large wheels, a set of separate brakes and a shield to protect the table base, all of which make transport significantly easier.
1	04498452	Fixed patient arm rest
1	14418438	MODULARIS Variostar MODULARIS Variostar is a compact and mobile therapy unit for shock wave applications in urological stone therapy (extracorporeal shock wave lithotripsy - ESWL). MODULARIS Variostar is equipped with the electromagnetic shock wave system 'C plus'. The standard support arm is used to move the therapy head into the undertable position and angulate it laterally at +/- 10°. A support arm is optionally available for the overtable and undertable positions. The menu-guided central hand control unit allows the setting of all relevant shock wave parameters, motorized table movement and C-arm angulation (with selected C-arms) as well as radiation release (fluoroscopy) and image storage (with selected C-arms). MODULARIS Variostar can optionally be combined with ACUSON X300 PE for localization and monitoring of stone disintegration.
1	14418473	Overtable/undertable treatment position# The flexible support arm extends the freedom of movement of the therapy head by the additional overtable therapy position. The support of overtable and undertable positions enables the treatment of all stones with the patient comfortably lying in the supine position. Moreover, the overtable therapy position is indispensable for comfortable positioning during ESWT applications. In the overtable therapy position, the therapy head can be angulated laterally at +/- 30° in order to find the optimum entry window for the shock wave into the patient's body.
1	14418472	Motorized gel position Motorized gel position for contact-free repositioning of patients and easy application of gel onto the shock wave head.
1	14404778	Extension Cable hand-held control The extension cable for the handheld remote control is 10 meters in length. With this cable the system can be operated from a greater distance, e.g. from behind a lead glass partition.
1	14409786	Interface for ECG VarioStar Fixation device for ECG triggering system.
1	14448083	Adaption Variostar Cios Fusion This adaptation enables the laser-guided alignment of the MODULARIS Variostar lithotripsy module with the X-ray C-arm Cios Fusion.
1	14455631	Cios Fusion Litho Cios Fusion is a compact, mobile C-arm system with a dynamic flat detector and touch user interface for fluoroscopy and acquiring single images with lithotripsy-specific functionality for combination with a MODULARIS Variostar.



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

SIEMENS REPRESENTATIVE
 Andy Grauling

Qty	Part No.	Item Description
		The mobile system is designed for use in cardiac/vascular surgery, gastroenterology, urology, emergency surgery, orthopedics and general surgery.
1	14455188	Flat Detector 30x30 High-resolution, dynamic flat panel detector with indirect converter technology (amorphous silicon) having a size of 30 cm x 30 cm, with a matrix of 1536 x 1536 pixels.
1	14455116	Dose measure. chamber System-integrated dose measuring chamber for displaying the dose area product or air kerma value. The cumulative dose area product is displayed for the current patient and saved under the patient data. The cumulated dose is automatically transferred to a radiation summary report and can be retrieved at any time. For each patient a cumulative value is saved in the patient database. Alternatively: Display of air kerma values
1	14455123	Mobi.workstation w.Flex pl. column Mobile workstation including monitor column with motorized height adjustment and 240° vertically rotatable monitors (-30° to +210°) for flexible positioning of the TFT displays with integrated cable routing and fold-up function for transport and park position.
1	14455126	2x High Bright TFT monitor Two 19" color TFT displays with high luminance for live and reference image display.
1	14455113	Dual DVI Video Splitter dual Connection for an external live monitor (monitor A) and an external reference monitor (monitor B) via DVI connection.
1	14455136	Standard foot switch Standard foot switch for radiation release and storing.
1	14455138	2D measurement function Measurement of angles and distances.
1	14455150	DICOM Send/Storage Commitment (StC) Digital, unidirectional image transfer of single images or complete folders to a network in DICOM format. Feedback from the image archive (Storage Commitment).
1	14455161	DICOM Print For sending and printing of images by means of a virtual filmsheet to a DICOM laser camera or printer. Provision of DICOM Print service for connection to a laser camera or a network printer (postscript-capable).
1	14455153	DICOM Worklist / MPPS Import of patient/examination data from an external RIS/HIS patient management system with DICOM MWL (Modality Worklist) as well as feedback on the examination status with DICOM MPPS (Modality Performed Procedure Step).
1	14455162	Printer Installation kit Installation kit for connecting Sony UP D 89x, UP 97x, and 99x printers
1	14455203	Skin Spacer Single-tank spacer.
1	SU_INITIAL_24	Initial onsite trng 24 hrs Up to (24) 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	SU_FREIGHT_COSTS	SU Freight Costs



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

SIEMENS REPRESENTATIVE
Andy Greuling

Qty	Part No.	Item Description
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_24	Follow-up Training 24 hours Up to (24) 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.

System Total: \$385,422



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

SIEMENS REPRESENTATIVE
 Andy Grauling

OPTIONS on Quote Nr:

1-IZAZDJ Rev. 1

OPTIONS for MODULARIS

All items listed below are OPTIONS and will be included on this system ONLY if initialed:

Qty	Part No.	Item Description	Extended Price	Initial to Accept
1	SONYUP991A D	Sony UP991AD printer - film and paper Black & White Hybrid Graphic Printer.	+ \$3,614	<i>X</i>

The UP-971AD is a black and white HYBRID graphic printer that supports both analog and digital applications. The UP-971AD has both an analog video input as well as a USB 2.0 high speed interface for digital printing. The UP-971AD offers a resolution of 325 dpi and print speed of about 8 seconds. * Dimensions: 12.4 x 5.2 x 12.0 inches. * Print Media: 210mm width roll. * Print Size: 10.5 x 7.87 inches (Digital/MAX). * Printing Method: Thermal Printing. * Resolution: 325 dpi.

Includes one year warranty through Sony.

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.

ACCESSORIES: Don't forget to ask us about our line of OEM imaging accessories to complete your purchase. All accessories can be purchased or financed as part of this order. To purchase accessories directly or to receive our accessories catalog, please call us directly at 1-888-222-9944 or contact your local Sales Representative.

COMPLIANCE: Compliance with legal and internal regulations is an integral part of all business processes at Siemens. Possible infringements can be reported to our Helpdesk "Tell us" function at www.siemens.com/tell-us.