



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

May 29, 2020

Robert A. Leandro, Partner
Parker, Poe, Adams and Bernstein, LLP
P.O. Box 389
Raleigh NC 27602-0389
robbleandro@parkerpoe.com

No Review

Record #: 3276
Business Name: Preventative Health and Wellness, LLC
Business #: 3216
Project Description: Acquire a CT scanner
County: Wake

Dear Mr. Leandro:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in that correspondence 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.

You may need to contact the Agency's Radiation Protection Section to determine if they have any requirements for development of the proposed project.

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.

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

Sincerely,

[Handwritten signature of Michael J. McKillip]

Michael J. McKillip
Project Analyst

[Handwritten signature of Martha J. Frisone]

Martha J. Frisone
Chief

cc: Radiation Protection 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
https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

**From:** [Frisone, Martha](#)  
**To:** [Waller, Martha K](#)  
**Subject:** FW: [External] Request for No Review Determination Letter  
**Date:** Tuesday, May 26, 2020 12:25:10 PM  
**Attachments:** [Request for No Review Determination re Preventative Health and Wellness, LLC.PDF](#)

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**Martha J. Frisone**

Chief

[Division of Health Service Regulation](#), Healthcare Planning and Certificate of Need  
[NC Department of Health and Human Services](#)

Office: 919-855-3879  
[martha.frisone@dhhs.nc.gov](mailto:martha.frisone@dhhs.nc.gov)

809 Ruggles, Edgerton  
2704 Mail Service Center  
Raleigh, NC 27699-2704

[Twitter](#) | [Facebook](#) | [YouTube](#) | [LinkedIn](#)

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**From:** Leandro, Robert A. <[robbleandro@parkerpoe.com](mailto:robbleandro@parkerpoe.com)>  
**Sent:** Tuesday, May 26, 2020 12:23 PM  
**To:** Frisone, Martha <[martha.frisone@dhhs.nc.gov](mailto:martha.frisone@dhhs.nc.gov)>  
**Subject:** [External] Request for No Review Determination Letter

**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](mailto:report.spam@nc.gov)

Martha,

Please see attached my client Preventative Health and Wellness, LLC's No Review Request. Hope you are well.

Robb

---

**Robert Leandro**  
Partner

Find our latest health care analysis [here](#).



PNC Plaza | 301 Fayetteville Street | Suite 1400 | Raleigh, NC 27601  
Office: 919.835.4636 | Fax: 919.834.4564 | [vcard](#) | [map](#)

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**Robert A. Leandro**  
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Charleston, SC  
Charlotte, NC  
Columbia, SC  
Greenville, SC  
Raleigh, NC  
Spartanburg, SC

May 26, 2020

**VIA ELECTRONIC MAIL**

Martha Frisone, Chief  
Healthcare Planning and Certificate of Need Section  
North Carolina Department of Health and Human Services  
2704 Mail Service Center  
Raleigh, NC 27699-2704  
Martha.Frisone@dhhs.nc.gov

Re: Request for No Review Determination

Dear Ms. Frisone:

This letter is intended to provide notice to the Healthcare Planning and Certificate of Need Section (the "Agency") that our client, Preventative Health and Wellness, LLC, whose sole member is Advanced Body Scan, LLC is planning to acquire a Siemens Computed Tomography ("CT") scanner.

Under North Carolina CON Law, it is our understanding that the acquisition of a CT scanner can trigger CON review only if: (1) the cost of acquiring the CT scanner exceeds \$750,000.00 and therefore meets the definition of "Major medical equipment" under N.C. Gen. Stat. §131E-176(14o); or (2) the acquisition of the CT scanner results in the development of a "Diagnostic Center" as defined by N.C. Gen. Stat. § 131E-176(7a). We believe that in this instance neither criteria are met and a CON is not required.

The cost of the CT scanner that our client plans to acquire is \$461,175.00 including tax and installation. See Attachment A. The total cost for the construction related to the space the CT Scanner will be located is \$36,299. See Attachment B. The construction cost of \$36,299.00 includes some costs that are not required to make the machine operational and therefore would not count toward the total costs as defined by the CON statute. However, even considering the entire cost of construction, the total acquisition cost of the CT scanner does not exceed \$500,000.00. There is also no other equipment that is being acquired or that is currently in use at the proposed location which has a value of \$10,000.00 or greater.

Based on these facts, the acquisition of the CT scanner does not constitute Major Medical Equipment or the development of a Diagnostic Center and therefore should not require a CON under North Carolina law. Accordingly,

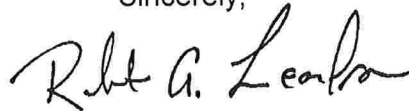
PPAB 3574487v1

May 26, 2020  
Page 2

we request that the Agency issue a written confirmation that our client's acquisition of the CT scanner is not subject to CON review.

I greatly appreciate your attention to this matter. If you have any questions, please feel free to contact me directly.

Sincerely,

A handwritten signature in black ink that reads "Robb A. Leandro". The signature is written in a cursive style with a large, prominent "R" and "L".

Robb Leandro

RAL:clr

Enclosure

# ATTACHMENT A



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

SIEMENS REPRESENTATIVE  
Stephen Argo  
craig.argo@siemens-healthineers.com

**PRELIMINARY PROPOSAL**

Customer Number: 0000310477

Date: 02/27/2020

**PREVENTIVE HEALTH AND WELLNESS LLC**  
2418 BLUE RIDGE  
Raleigh, NC 27607

Estimated Delivery Date:

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.

POS service agreement required.

This Quotation 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.

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Quote Nr. CPQ-131485 Rev. 0

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**SOMATOM go.All**

All items listed below are included for this system:

Qty	Part No.	Item Description
1	14460595	<p><b>SOMATOM go.All</b></p> <p>As a member of the SOMATOM go. platform, the SOMATOM go.All enables users of all skill levels to confidently take on advanced CT procedures. The scanner features a unique tablet-based mobile workflow, user guidance with our GO technologies, and exclusive innovations such as Tin Filter low dose technology.</p>
1	14460605	<p><b>SW Base Package</b></p> <p>SW Base Package</p> <p>Scan&amp;GO mobile workflow, including tablet, remote control, camera, and a new workplace design</p> <p>Check&amp;GO flags problems with scan coverage or contrast distribution as they occur</p> <p>Recon&amp;GO reduces post-processing to just one click, with: Inline Anatomical Ranges, Inline Table and Bone Removal, Inline Vessel Ranges and Multi Recon-performing multiple reconstructions in one step</p> <p>CT View&amp;GO provides a variety of clinical applications and tools for smooth reading in just one workflow</p>

## PRELIMINARY PROPOSAL

### SAFIRE

SOMATOM go. scanners achieve higher efficiency with in dose reduction with Sinogram Affirmed Iterative Reconstruction while maintaining excellent image quality

### Interleaved Volume Reconstruction

Enhances spatial sampling in z-direction, independent of pitch

### CARE Dose4D, CARE kV, 10 kV Steps, CARE Child

Personalized dose control tools that allow you to increase consistency of low dose CT scanning techniques across all technologists

### Endoscopic View

Simulated views of e.g. the inside of bronchi, colon and any other hollow structures

### Dual Spiral Dual Energy and Dual Energy ROI

syngo Single Source Dual Energy Scan mode option offers the possibility to acquire two spiral data sets in sequence at different energies

### HD FoV\*\*

Enables a field of view up to 70 cm, which is optimal for visualization of obese patients and those that are positioned outside the CT isocenter

\*In clinical practice, the use of SAFIRE may reduce CT patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task

\*\* The image quality for the area outside the standard 50 cm scan field does not meet the image quality specifications shown in the technical data sheet and image artifacts may appear, depending on the anatomy scanned

1 14460606

### Scan&GO wireless edition

Includes Scan&GO Tablet and Remote Scan Control. Built around a new mobile workflow, the SOMATOM go. platform features a line-up of innovative solutions – tablet, remote control, camera, and a new workplace design – that bring an unparalleled level of flexibility and mobility to daily CT routines. The solutions also enhance patient comfort for potentially higher levels of patient satisfaction.

The lightweight, high-resolution tablet gives our customers total freedom over how they work: only a few steps for the entire scan.

1 14468330

### Cardio Base Package

This bundle of software and hardware delivers a robust set of basic cardiac scanning functionality that takes advantage of the fast 0.33s rotation speed of the scanner. This package includes:

#### Physiological Measurement Module

This module allows the user to connect a 3 Channel ECG cable for ECG controlled cardiac acquisition.

#### ECG cable

Item includes 3 channel ECG cable according to IEC1 (European color coding).

#### Cardio Spiral

The option supports adaptive retrospective ECG-gated spiral scanning to obtain CT images of the heart in defined phases of the cardiac cycle.



## PRELIMINARY PROPOSAL

### BestPhase

A software dedicated to automatically detect the optimal phase for motionless coronary visualization.

### Cardio Quick Sequence

Prospective ECG triggered quick cardiac scan mode for coronary CaScoring imaging.

### syngo.CT CaScoring

The Calcium Scoring application supports volumetric processing of the data and treats individual calcified lesions as 3D objects. For effective visualization the Calcium Scoring application allows axial images to be displayed together with fast, interactive MIPs. On each image the user can mark calcified regions in up to four coronary arteries. The tabular display showing the score of the four arteries is updated automatically.

-Supports all the usual quantification algorithms: Agatston scoring, volumetric scoring and calcium mass quantification. The effect of overlapping slices is compensated. The volume and mass can be determined on the basis of basic volumetric scoring or volumetric scoring with continuous interpolation. The calcium mass is determined in equivalent CaHA units and is calibrated automatically for SOMATOM systems via the scan mode. The threshold for identifying coronary calcifications is configurable.

These features are supported by an integrated electrocardiography (ECG) signal displayed on the tablet.

1 14460624

### High-speed 0.33 s

This option provides a rotation speed of down to 0.33 sec per rotation, for outstanding image quality and very high scan speeds. Fast gantry rotation times are the prerequisite for highest temporal resolution and are therefore essential for brilliant, motion free cardiovascular imaging. With the temporal resolution of 165ms, this CT is especially suitable for cardiac examinations and fast scanning.

1 14460623

### iMAR

The iMAR metal artifact reduction algorithm combines three successful approaches (beam hardening correction, normalized sinogram inpainting and frequency split). This makes it possible to reduce metal artifacts caused by metal implants such as coils, metal screws and plates, dental fillings or implants. Along with the algorithm comes the simple user interface of iMAR enabling easy reconstruction of clinical images with reduced metal artifacts. iMAR can be combined with iterative reconstruction methods.

1 14460617

### FAST IRS

Including FAST AWP and FAST IRS

1 14460609

### 227 kg Patient Table

Patient table with 500 lb / 227 kg weight limit

1 14460613

### Foot Switch for Pat.Table control

Additional flexibility with a foot switch that controls patient table movements only.

1 14460643

### Table Accessories Set

More table accessories for further flexibility based on the clinical needs. Includes table side rails, storage box and infusion holder.

1 14461354

### Multipurpose Positioning Mattress

Multipurpose Positioning Mattress is compatible with the dedicated scanner patient table. The mattress includes a foam insert and makes it easier to slide patients on and off the table. This way, patient positioning can be further optimized.

**PRELIMINARY PROPOSAL**

This mattress can also be used with an optional syngo Osteo CT software and phantom to enable bone mineral density measurements.

1 14460614

**Table Extension**

Table extension

1 14460647

**UPS**

UPS. An uninterrupted power supply, for the syngo Acquisition Workplace in the event of network fluctuations and brief power failures.

1 14460793

**Computer Desk 1200 mm**

CT desk designed to accommodate the control components and color monitor(s).

1 CT\_GO\_STELL  
AR

**Stellar Low Noise Technology Detector**

The Stellar detector's high-end technology includes fully integrated components. As a result, Stellar detector technology keeps electronic noise low, increases dose efficiency and improves spatial resolution. The smart configuration of the detector elements simplifies access, eases maintenance, and increases scanner uptime. For SOMATOM go scanners, the Stellar detector features a 3D anti-scatter collimator for even more efficient optimization of X-ray energy.

1 SURE\_VIEW

**SureView**

Provides exceptional image quality at any pitch setting, enabling you to scan faster because you can scan at any pitch without degrading image quality

1 CT\_LUNGIMAGI  
NGGO

**Lung Imaging**

Lung Imaging Go: For well over a decade, CT has been recognized and used as the standard of care for lung nodule visualization and sizing. This is due to CT's spatial resolution, geometric accuracy, and ability to create various reconstructions and 3D views. The high contrast environment in the chest between the lungs and the nodules makes for a relatively easy visualization task for clinicians using CT images. Recent advances in CT technology have allowed these scans to be effectively performed at lower doses, higher resolutions, and faster scan times. The SOMATOM go.Platform leverages Tin Filter Technology to further enhance the delivery of low dose lung cancer screening for high risk populations\*. The SOMATOM go scanners are delivered with specific scan protocols to provide low dose lung cancer screening exams that use Siemens-exclusive Tin Filter Technology to reduce unnecessary radiation. These default protocols also utilize Siemens proprietary dose reducing features such as CARE Dose4D™, automatic exposure control technology, that further modulates and adapts dose for every patient, for high image quality at low dose. The SOMATOM go scanners come with default low dose lung imaging protocols below 1 mSv. \*As defined by professional medical societies.

1 ACCESS\_PROT  
ECT

**Access Protection**

Scan Protocols are password protected allowing only authorized staff members to access and permanently change protocols

1 NEMA\_XR-29

**NEMA\_XR-29 Standard**

This system is in compliance with NEMA XR-29 Standard Attributes on CT Equipment Related to Dose Optimization and Management, also known as Smart Dose.

1 CT\_PM

**CT Project Management**

A Siemens Project Manager (PM) will be the single point of contact for the implementation of your Siemens equipment. The assigned PM will work with the customer's facilities management, architect or building contractor to assist you in ensuring that your site is ready for installation. Your PM will provide initial and final drawings and will coordinate the scheduling of the equipment, installation, and rigging, as well as the initiation of on-site clinical education.

**PRELIMINARY PROPOSAL**

- 1 CT\_BUDG\_ADD  
L\_RIG **Budgetary Add'l/Out of Scope Rigging @ \$4,000**
- 1 CT\_BTL\_INSTA  
LL **CT Standard Rigging and Installation**
- 1 4SPAS014 **Low Contrast CT Phantom & Holder**
- 1 PSPD250480Y3  
K **Surge Protective Device (SPD)**
- 1 CTSPER01 **CT Slicker**  
Thermoseal seams and flaps deflect fluids, reducing contaminant penetration into the cushion and table. Contaminants are retained on the tabletop or shunted to the floor. Cleanup is faster, more thorough, and contaminant build-up is reduced. Built using heavy, clear, micro matte vinyl, and top grade hook and loop fastening strips (Velcro) to better fit the specified table. Custom vinyl resists tears and minimizes radiologic interference. Latex free. Set includes CT Skirts.  
  
Includes warranty from RADSCAN Medical.
- 1 CT\_EDUOPTIO  
N3 **Clinical Education & Training: Option 3**  
Siemens offers multiple options for clinical education and training on your new system. These options enable a more personalized approach to the introduction to system operation, features, and benefits and will help ensure that your technologists and physicians have the opportunity to engage in the level of training that best meets your current clinical needs and business objectives.  
  
The following items are the education and training modules are highly recommended for the operation of your new Siemens system and are most effective for sites where technologists and/or physicians have limited experience on Siemens' systems. With a focus on routine procedures, this option also provides additional opportunities to further increase efficiencies.
- 1 CT\_GOBASIC\_  
CLS\_NTL **CT Go Basic Class, No Travel**  
Tuition for (1) imaging professional to attend a 2-day classroom course at Siemens Training Center in Cary, NC. The objectives of this course are to introduce the user to the Siemens SOMATOM go. platform, new patient-centric mobile workflow and technologies including Scan&Go, Check&Go, Recon&Go, CT View&Go, Guide&Go. Users will be able to understand the effect of choosing various parameters on image quality and dose. The instructor will combine didactic interactive discussions with hands-on training of key CT system operating hardware and workflow software functions. This class excludes airfare and lodging. 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.
- 1 CT\_INITIAL\_32 **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.
- 1 CT\_FOLLOWUP  
\_16 **Follow-up training 16 hrs**  
Up to (16) hours of follow-up on-site clinical education training, scheduled



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

SIEMENS REPRESENTATIVE  
Stephen Argo  
craig.argo@siemens-healthineers.com

**PRELIMINARY PROPOSAL**

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 SY\_PR\_TEAMP  
LAY

**teamply Welcome & Registration Package**

teamply is a cloud-based network that brings together your imaging modality users, the systems' dose and utilization data, and the users' expertise to help you improve the delivery of care to your patients. Basic features are provided free of charge. Premium features (benchmarking, non-Siemens devices) are provided on a trial basis for three months at no charge, and may be used thereafter on a subscription fee basis.

To register: <http://teamply.siemens.com/#/institutionRegistration/1>

**System Total** \$ 430,000



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

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### 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

craig.argo@siemens-healthineers.com

# ATTACHMENT B

# ModernSouth

CONSTRUCTION COMPANY

February 26, 2020

SCHEMATIC CT ROOM COST MODEL  
 RALEIGH, NC  
 CT ROOM / CONTROL ROOM / EQUIPMENT ROOM  
 NOT A BID

	Unit	Quantity	Group Total
<b>Division 6 Woods and Plastics</b>			
<b>6400 Cabinetry and Millwork</b>			
Uppers, Lowers, Top	Inft	4	
Countertop Desk	Inft	4	
			\$1,140.00
<b>Division 8 Doors and Windows</b>			
<b>8100 Hollow Metal Frames and Doors</b>			
HM Lead-lined Window Frame	each	1	
HM Lead-lined Door Frame	each	2	
HM 3 side Frames	each	1	
			\$2,680.00
<b>8200 Wood Doors</b>			
Wood Door - Lead-lined	each	2	
Wood Door - Standard	each	1	
			\$2,435.00
<b>8700 Finished Hardware</b>			
Door Hardware - Lead Shield	each	3	
Door Hardware Install	each	3	
			\$885.00
<b>8800 Glass and Glazing</b>			
Lead Lined Viewing Window	lsum	1	
			\$520.00
<b>Division 9 Finishes</b>			
<b>9200 Gypsum Walls</b>			
Mtl Stud, Lead Lined Gyp One Side	sf	684	
Mtl Stud, (Less Lead-lined), Std Gyp 1 Side	Inft	28	
Mtl Stud, Std Gyp 1 Side	Inft	23	
Standard Gyp On Exist Studs	Inft	23	
Lead lined ceiling	sf	324	
			\$18,581.00
<b>9400 Resilient Flooring</b>			
Vinyl Flooring	sf	471	
Resilient Base	Inft	1	
			\$1,179.15
<b>9500 Acoustical Ceiling</b>			
Acoustical Ceiling	sf	120	
			\$240.00
<b>9900 Painting and Wallcovering</b>			
Painting	lsum	1	
			\$800.00
<b>Division 15 Mechanical Systems</b>			
<b>15100 Sprinkler System</b>			
Sprinkler	lsum	1	
			\$600.00
<b>15500 HVAC</b>			
HVAC Equipment and Duct / Dampers	lsum	1	
			\$1,200.00
<b>Division 16 Electrical</b>			
<b>16000 Electrical Systems</b>			
Electrical Power and Lighting	lsum	1	
Fire Alarm	lsum	1	
			\$3,350.00
			\$33,610.15
	Material	\$5,550.00	
	Labor	\$0.00	
	Subcontract	\$28,060.15	
	Equipment	\$0.00	
	Other	\$0.00	
Cost of Work SUBTOTAL		\$33,610.15	
Add-ons	FEE & OH	\$2,688.81	8.00%
	SUBTOTAL	\$2,688.81	
<b>BASE TOTAL</b>		<b>\$36,298.96</b>	