



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

September 6, 2013

Denise M. Gunter
Nelson, Mullins, Riley & Scarborough, LLP
380 Knollwood Street, Suite 530
Winston-Salem NC 27103

Exempt from Review - Replacement Equipment

Facility: Chapel Hill Diagnostic Imaging, LLC
Project Description: Replace existing Siemens 1.5T MRI Scanner with a Siemens 1.5T MRI scanner
County: Orange

Dear Ms. Gunter:

In response to your letter of August 26, 2013, 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 Siemens 1.5T MRI scanner [Serial # 25460] to replace the existing Siemens 1.5T MRI scanner [Serial # 25065]. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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,

Michael J. McKillip
Project Analyst

Craig R. Smith, Chief
Certificate of Need Section

Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-733-8139

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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Denise M. Gunter
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August 26, 2013

Hand Delivered

Craig R. Smith, Chief
Martha J. Frisone, Assistant Chief
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
809 Ruggles Drive
Raleigh, North Carolina 27603

Received by
the CON Section
AUG 26 2013

Re: Notice of Replacement Equipment for Chapel Hill Diagnostic Imaging, LLC
Fixed MRI Unit - Orange County)
Health Service Area IV

Dear Craig and Martha:

Chapel Hill Diagnostic Imaging, LLC ("CHDI") owns a GE 1.5T HiSpeed MRI scanner (the "Existing Scanner"), located at 110 S. Estes Drive, Chapel Hill, North Carolina in Orange County. On June 30, 2013, CHDI's facility flooded during a severe storm. See news article attached as Exhibit A describing flooding in the Estes Drive area of Chapel Hill. As a result of the flooding, the Existing Scanner was damaged beyond repair and must be replaced. CHDI proposes to acquire a refurbished Siemens Avanto MRI unit to replace the flood damaged Existing Scanner (the "Replacement Scanner"). The capital cost for this project is \$698,000. This includes all costs essential to acquiring the replacement equipment and making it operational at CHDI. See Exhibits B and C (equipment quote and capital cost form). CHDI does not expect to incur any construction costs related to this replacement; however, in an abundance of caution, CHDI has included a \$50,000 contingency in the capital cost form should any such expenses arise.

This proposal meets the definition of "replacement equipment" as set forth in N.C. Gen. Stat. § 131E-176(22a) because:

Craig R. Smith
Martha J. Frisone
August 26, 2013
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1. The cost of the Replacement Scanner and the cost of all activities essential to acquiring and making operational the replacement equipment are less than \$2 million;
2. The Existing Scanner was in use at the time the natural disaster took place;
3. The Existing Scanner will be removed from North Carolina when the Replacement Scanner has been installed and will not be brought back to North Carolina without CON approval; and
4. The sole purpose of this proposal is to temporarily replace comparable medical equipment.

Further, this proposal meets the requirements of 10A NCAC 14C .0303(d) because:

- The Replacement Scanner has comparable technology to the Existing Scanner;
- The Replacement Scanner is functionally similar and is used for the same diagnostic or treatment purposes as the Existing Scanner and is not used to provide a new health service; and
- The Replacement Scanner will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the Existing Scanner is replaced.

None of the exclusions in 10A NCAC 14C .0303(e) applies here.

An equipment comparison form is attached as Exhibit D.

Based on the foregoing, CHDI respectfully requests that the CON Section confirm in writing that: (1) the above-referenced replacement is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7); and (2) the above-referenced replacement for the Existing Scanner is not a new institutional health service that requires a CON pursuant to N.C. Gen. Stat. § 131E-183.

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Martha J. Frisone
August 26, 2013
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Thank you for your time and attention.

Sincerely,

Denise M. Gunter with permission
Denise M. Gunter *by J. Blakely Kiefel*


Enclosures

Chapel Hill cleans up, inspects flood damage

Posted: June 30

Updated: July 2

Authorities fanned out across water-logged Chapel Hill on Monday to inspect property damage left from a soggy night of near-record rainfall and flash flooding.

More Info 



[Get severe weather alerts on the go](#)

Teams of firefighters, police officers and public works employees were getting an accurate count of how many homes and vehicles were battered by floodwater, and checking for structural and environmental damage caused by heavy storms that rolled through the region.

They were also working to determine whether the area qualifies for disaster relief funds.

"Emergency crews are doing everything within their expertise to make the town a safe and livable place for all," town spokeswoman Lisa Edwards said in a statement. "Emergency crews will be monitoring situations throughout the town during the next 48 hours."

A total of 4.66 inches of rain fell in Chapel Hill on Sunday, according to data from the State Climate Office. Another 2 to 4 inches of rain could hit the Triangle by Tuesday, bringing the potential for more flooding.

Dozens of counties, including Orange, Durham and Wake, remain under a flash flood watch through 6 p.m. Wednesday.

"What we're most concerned about is the same area seeing the same rain over and over," WRAL meteorologist Elizabeth Gardner said. "That's what happened in Chapel Hill Sunday."

Heavy rains and flooding Sunday affected an estimated 150 people in Orange County. Forty people had to be rescued, including 25 residents from Rocky Brook Mobile Home Park on South Greensboro Street in Carrboro.

Residents were also forced to leave their homes in Camelot Village, near University Mall, on Estes Drive in Chapel Hill. Estes Drive was closed, and Orange County Emergency Services reported the parking lot of Shops at Eastgate was also under water.

Chapel Hill firefighters said they responded to 56 emergency calls in a 24-hour period.

Bolin Creek and multiple locations on Franklin Street were flooded with as much as 4 to 6 feet of water, and numerous cars were stalled in water.

There were also downed trees and power outages. At one point Sunday night, about 2,100 Duke Energy Progress customers were without electricity in Durham; about 1,000 were without power in Orange County.

"I'm out here because I can't get home," Chapel Hill resident Grace Turrentine said Sunday. "I've never seen this much water where it's not supposed to be, in my life."

The Triangle Chapter of the American Red Cross opened a shelter at Smith Middle School, 9201 Seawell School Road in Chapel Hill. People with special needs, as well as pets, are being accommodated. About 40 people had taken advantage of the shelter Sunday night, American Red Cross officials said.



The water flushed Michael Stephenson out of his home in Camelot Village. His furniture, belongings and car were all damaged or destroyed.

"I won't be living here anymore," he said. "It is just a crazy experience."

Dwayne Hayes spent the night at Smith Middle School after fleeing his flooded condominium at the complex on Estes Drive. He said he's lived in Chapel Hill since 1975 and has seen serious flooding only once before, during a hurricane.

"This one came on us fast. The water rose so quickly, we couldn't even leave our apartments because you could not open the doors," he said. "I've never seen anything like this."

Hayes said the water was "like a river" and waist deep in some areas. He's not sure when he will be able to return home.

"Everything I own is wet," Hayes said. "This is difficult."

Brian Owens also evacuated from Camelot Village on Sunday night as water rushed into his residence.

"It was pretty much a mad scene," Owens said. "Chaos everywhere."

He returned home Monday morning to find floodwater had displaced parked cars and soaked belongings.

Seventy-six of the 116 units at Camelot Village, which is a mix of privately owned and managed units, flooded Sunday. Renters said Monday they have been told to remove their property so repair work can begin.



Chapel Hill officials on Monday closed the first floor town hall and the playgrounds at Umstead Park and the Chapel Hill Community Center because of flooding or debris cleanup.

Granville Towers at the University of North Carolina at Chapel Hill also took on several feet of water in the basement. Cleanup crews were pumping out the water Monday afternoon from the west tower. No students are living the building during summer break, officials said.

Flooding also caused problems Sunday in Durham, where cars were stalled along Garrett and Hope Valley roads. Roxboro Road was also flooded in multiple spots.

In Chatham County, rain fell moderately over areas south of Pittsboro, causing flooding and road closures on Mount Gilead Church Road and Sanford Road.

Raleigh was spared from serious flooding.

Crabtree Creek, which often floods the Crabtree Valley Mall property during heavy rain, was muddy and swollen Monday but stayed within its banks. The mall closed the lowest parking levels as a precaution, but stores remained open.

The chance for stormy weather will linger early in the work week, although the temperatures will hover in the mid-80s instead of low 90s. The humidity will remain high, Gardner said.

"More is definitely coming," she said. "We're in this pattern where it's like someone opened up the fire hose and aimed it at North Carolina."

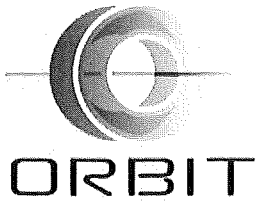
The National Weather Service advises motorists to refrain from driving into areas where water covers roads. As little as 6 inches of water can cause a driver to lose control. Two feet of rushing water can carry away most vehicles, including SUVs and pickups.

Skies over the Triangle were clear before dawn Monday, but heavy rain was falling to the west and moving east. Moisture flowing up from the south could fire up additional storms.

The chance of thunderstorms will decrease by the weekend, which is expected to be dry and hot. Temperatures will climb back into the 90s on Saturday and Sunday.

Reporters: Leyla Santiago, Tara Lynn, Sloane Heffernan, Renee Chou
Web Editors: Bridget Whelan, Kelly Gardner, Angie Basiouny

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**Orbit Medical Technologies, Inc.**

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Fax: 1-866-596-7188

Quotation**Quote #: 1312****Date: August 14, 2013**

Customer: CHAPEL HILL DIAGNOSTIC IMAGING, LLC
110 South Estes Drive, Chapel Hill, NC 27514
C/O MedQuest Associates, Inc.,
3480 Preston Ridge Road, Alpharetta, GA 30005

This quotation constitutes Orbit Medical Technologies offer to sell the listed products described herein. This quotation shall not bind Orbit Medical Technologies until a purchase agreement has been countersigned by an authorized representative in the corporate offices in Harvey, Illinois.

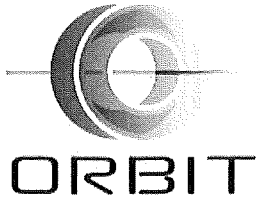
System Being Purchased:

Refurbished 2005 Siemens Magnetom AVANTO 1.5T MRI system

System Serial Number: **25460**

System Highlights:

- Tim [76*32]
- Software: Syngo MRB17
- Gradient Strength: SQ-engine (45 mT/m @ 200 mT/m/sec)
- TIM Application Suite
- Syngo General License
- Matrix Mode
- 3D Usage License
- 3D MPR
- 3D MIP
- 3D SSD
- Argus Viewer
- Worklist
- MDDW
- PhoenixZip
- Syngo Remote Assist
- Inline 3D Distortion Correction
- Image Filter Software
- MPPS
- 3D Distortion Correction



Orbit Medical Technologies, Inc.

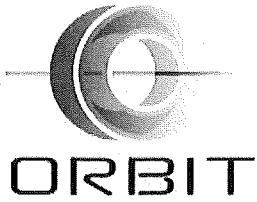
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- **Neck Matrix**



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Purchase Price: \$600,000 (Six Hundred Thousand Dollars)

The quoted price includes the following services:

1. De-installation and rigging out the existing Siemens Avanto 1.5T MRI from site
(Assuming Orbit will purchase the system or ship back to Orbit's warehouse for staging and evaluation purposes)
2. Delivery, rigging, and installation of the quoted Siemens Avanto MRI system
3. 90 Days parts and labor warranty

This pre-owned, refurbished system is offered on first come, first served basis. Subject to prior sale and availability.

PROJECT CAPITAL COST

A. <u>Site Costs</u>		
(1)	Full purchase price of land # Acres _____ Price per Acre \$ _____	<u>\$Not Applicable</u>
(2)	Closing costs	<u>\$Not Applicable</u>
(3)	Site Inspection and Survey	<u>\$Not Applicable</u>
(4)	Legal fees and subsoil investigation	<u>\$Not Applicable</u>
(5)	Site Preparation Costs [Include]	
	Soil Borings	
	Clearing and Grading	
	Roads and Parking	
	Sidewalks	
	Water and Sewer	
	Excavation and Backfill	
	Termite Treatment	
	Sub-Total Site Preparation Costs	<u>\$Not Applicable</u>
(6)	Other (Specify)	<u>\$Not Applicable</u>
(7)	Sub-Total Site Costs	<u>\$ Not Applicable</u>
B. <u>Construction Contract</u>		
(8)	Cost of Materials [Include]	
	General Requirements	
	Concrete/Masonry	
	Woods/Doors & Windows/Finishes	
	Thermal & Moisture Protection	
	Equipment/Specialty Items	
	Mechanical/Electrical	
	Sub-Total Cost of Materials	\$ _____
(9)	Cost of Labor	\$ _____
(10)	Other	\$ _____
(11)	Sub-Total Construction Contract	_____ <u>\$0</u>
C. <u>Miscellaneous Project Costs</u>		
(12)	Building Purchase	\$ _____
(13)	Fixed Equipment Purchase/Lease	<u>\$ 648,000 (includes sales tax)</u>
(14)	Movable Equipment Purchase/Lease	\$ _____
(15)	Furniture	\$ _____
(16)	Landscaping	\$ _____
(17)	Consultant Fees	
	Architect/Engineering Fees	\$ _____
	Legal Fees	\$ _____
	Market Analysis	\$ _____
	Other	
	Total Consultant Fees	\$ _____
(18)	Financing Costs (e.g. Bond, Loan, etc.)	<u>\$Not Applicable</u>
(19)	Interest During Construction	<u>\$Not Applicable</u>
(20)	Other (Contingency)	<u>\$ 50,000</u>
	Other (MRI Rigging)	<u>\$ Included</u>
(21)	Sub-Total Miscellaneous	\$ _____
D.	Total Capital Cost of Project (Sum A-C above)	<u>\$698,000</u>
The cost of the MRI unit includes deinstall of the existing scanner and installing the new scanner.		

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

N/A

(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.

Lee Moore

(Proponent)

VP, GENERAL COUNSEL

(Title of Officer)

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	MRI Scanner	MRI Scanner
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating of MRI's	1.5T	1.5T
Model Number	Avanto	Avanto
Serial Number	25065	25460
Provider's Method of Identifying Equipment	Serial ID or VIN# N/a	Serial ID or VIN# 25460
Specify if Mobile or Fixed	Fixed	Fixed
Date of Acquisition of Each Component	2004	TBD
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	Used
Total Capital Cost of Project (Including Construction, etc)	\$	\$698,000 (includes sales tax and contingency)
Total Cost of Equipment	\$1,750,000	\$600,000
Fair Market Value of Equipment	\$	\$
Net Purchase Price of Equipment	N/A	N/A

Locations Where Operated	Chapel Hill Diagnostic Imaging 110 S. Estes Drive Chapel Hill, NC 27514	
Number of Days in Use/To be Used in N.C. Per Year	365	
Percent Change in Patient Charges (by Procedure)	N/A	0%
Percent Change in Per Procedure Operating Expenses	N/A	0%
Type of Procedures Currently Performed on Existing Equipment	MRI Scans	MRI Scans
Type of Procedures New Equipment is Capable of Performing	MRI Scans	MRI Scans