

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

December 20, 2012

G. Wilson Holmes, Jr. King's Medical Group 1549 Wheaton Way Concord, NC 28027

RE:

Inquiry / King's Medical Company and Watauga Medical Center / Replace Hitachi Airis II Elite 0.3T

MRI Scanner with Siemens Avanto 1.5T MRI Scanner / Watauga County

FID#: 933533

Dear Mr. Holmes:

In response to your correspondence of December 7, 2012, the Certificate of Need Section has determined that:

- 1. In 2004, King's Medical Company and Watauga Medical Center jointly filed a CON application for the Hitachi Airis II Elite 0.3T MRI Scanner to be located in Watauga Medical Center.
- 2. The terms of the lease stated in the CON application indicate that upon completion of the lease term Watauga Medical Center will be the sole owner of the MRI machine.
- 3. At the time of the proposed replacement of the existing MRI Scanner, the lease terms are complete and King's Medical Company has no ownership in the existing MRI machine.
- 4. There is therefore no change in ownership associated with the replacement of the existing MRI Scanner.
- 5. Accordingly, 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 Avanto 1.5T MRI Scanner to replace the existing Hitachi Airis II Elite 0.3T MRI Scanner. 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. 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 inventory, if not already provided.

Moreover, you need to contact the Construction and Acute and Home Care Sections to determine if they have any requirements for development of the proposed project.



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

Julie Halatek Project Analyst

Julie Halatek

Craig R. Smith, Chief Certificate of Need Section

cc: Nadine Pfeiffer, Medical Facilities Planning Section, DHSR

Azzie Conley, Acute and Home Care Section, DHSR

Steven Lewis, Construction Section, DHSR



King's Medical Company 1894 Georgetown Road Hudson, Ohio 44236 Watauga Medical Center 336 Deerfield Road Boone, NC 28607

December 7, 2012

Mr. Craig R. Smith, Chief
Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health and Human Services
Edgerton Building
809 Ruggles Drive
Raleigh, NC 27603



Re: Exempt from Review—Watauga Medical Center & King's Medical Company/Replace Hitachi Airis II Elite 0.3T MRI Scanner with Siemens Avanto 1.5T MRI Scanner/Watauga County

Dear Mr. Smith:

This is a joint letter from Watauga Medical Center ("Watauga") and King's Medical Company ("KMC"). Pursuant to G.S. 131E-184(a)(7), this letter provides notice that Watauga desires to acquire an MRI scanner from KMC in replacement of an existing MRI scanner. Below, and in the Exhibits to this letter, we provide the relevant information related to the replacement. Based on this information, we request that the Certificate of Need Section confirm to us in writing that the proposed acquisition of the replacement equipment is exempt from certificate of need review. We also request confirmation that Watauga may rent and operate a temporary mobile MRI scanner provided by KMC during the period of accomplishing the replacement.

DISCUSSION

1. The Existing MRI Equipment

The Section issued a certificate of need (the "CON") to Watauga and KMC for Project Identification Number D-6652-02 that authorized them to acquire and operate a Hitachi Airis II Elite 0.3T MRI Scanner at Watauga (the "Existing MRI Equipment"). The Existing MRI Equipment was purchased in November 2005 and was new at the time of the purchase. The Existing MRI Equipment is located at Watauga's Outpatient Imaging Center in Boone, North Carolina. The Existing MRI Equipment is currently in use and has been continuously in service since its installation at Watauga. Watauga uses the Existing MRI Equipment to provide medical imaging services through nuclear magnetic resonance. (As explained below, KMC intends to relinquish its rights in the CON in connection with the replacement.)



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Upon the de-installation of the Existing MRI Equipment, KMC will have it removed from the State, and will not operate it again in the State except in accordance with the CON laws.

2. The Replacement MRI Equipment

A. Details Concerning the Replacement MRI Scanner Equipment

The replacement MRI scanner equipment is a refurbished Siemens Avanto 1.5T MRI Scanner (the "Replacement MRI Equipment"). *See* Exhibit A (description of scanner). Watauga will acquire the Replacement MRI Equipment from KMC by purchase.

The Replacement MRI Equipment will be located at Watauga Medical Center, Radiology Department, located at 336 Deerfield Road, Boone, North Carolina. The Replacement MRI Equipment will require only limited construction, as reflected below.

The Replacement MRI Equipment will be functionally similar to, and used for the same treatment purposes as, the Existing MRI Equipment. The Replacement MRI Equipment will have the same basic technology as the Existing MRI Equipment and will be used to provide medical imaging services through nuclear magnetic resonance.

The acquisition of the Replacement MRI 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 MRI Equipment is acquired. For additional information comparing the Existing MRI Equipment and the Replacement MRI Equipment, please see Exhibit B (Equipment Comparison Chart).

B. Details Concerning the Replacement Costs

The total cost of the Replacement MRI Equipment is less than \$2 million, including the cost of all activities essential to acquiring and making operational the Replacement MRI Equipment. Specifically, the total cost related to the replacement is \$1,332,793.82, as follows:

\$ 850,000.00		Replacement MRI Equipment
83,922.38		Financing Cost For Replacement MRI Equipment
148,871.44		Construction (\$123,871.44) and Architect/Engineering Fees (\$25,000)
70,000.00		De-installation, Delivery, and Installation, and Training (for
180,000.00	Nation of the latest and the latest	Replacement and Temporary Scanners) Rental of temporary mobile scanner (<i>see</i> discussion below)
Total: \$1,332,793.82		



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See Exhibit C (Capital Cost Chart) and Exhibit B (Equipment Comparison Chart). In both this letter and the Exhibits, we have included for convenience the rental cost of the temporary mobile MRI scanner, even though we believe the inclusion of this cost in not statutorily required.

Watauga will finance the purchase of the Replacement MRI Equipment and listed the interest cost (\$83,922.38) above. There will be no financing costs associated with the construction for this project. Because Watauga is exempt from sales tax, no sales tax will be added to the purchase price or to any other item of cost related to the Replacement MRI Equipment.

3. Temporary Mobile MRI Scanner

In connection with the acquisition of the Replacement MRI Equipment, Watauga plans to rent a temporary mobile MRI scanner from KMC for up to three months at \$60,000 per month—which results in a total rental of \$180,000 as reflected above. Watauga will use the temporary scanner to provide MRI services only during the interim period between the de-installation of the Existing MRI Equipment and installation and placing into operation of the Replacement MRI Equipment. Hence, Watauga will use the temporary scanner to continue the existing services provided to and required by Watauga's patients. The temporary scanner will be located at 336 Deerfield Road, Boone, North Carolina. Once the Replacement MRI Equipment is operational, KMC will remove the temporary MRI scanner from the State.

4. Relinquishment of CON Rights

In connection with Watauga's acquisition of the Replacement MRI Equipment from KMC, KMC will relinquish all of its rights under the CON, including such rights that otherwise would apply to the Replacement MRI Equipment. Watauga will own and operate the Replacement MRI Equipment in accordance with the applicable requirements of the CON.

CONCLUSION

Based on the information in this letter and the attached Exhibits, we look forward to receiving confirmation from you that the proposed replacement of the Existing MRI Equipment with the Replacement MRI Equipment is exempt from certificate of need review pursuant to G.S. 131E-184(a)(7), and that in connection with the replacement, Watauga may rent and operate the temporary mobile MRI scanner from KMC as provided above. If you have any questions or need additional information, please let us know.

Sincerely

King's Medical Company

Watauga Medical Center

Enclosures

EXHIBIT "A"

Siemens 1.5T Avanto MRI System

Magnet Type	1.5T, 3630 kg, 150cm long, E.I.S., zero boil off				
Gradient Strength	33 mT/m per axis (57mT/m vector summation)				
Gradient Slew Rate	125 T/m/s per axis (216T/m/s vector summation)				
Software Release	Syngo VB-15				
Storage Type/ Capacity					
Number of Images	110,000 images				
Reconstruction Speed	1002 recons/second (256 X 256)				
	Body Matrix Coil (x2)				
	Head Matrix Coil				
	Neck Matrix Coil				
	Spine Matrix Coil				
	CP Flex Coil, Large				
Surface Coils:	CP Flex Coil, Small				
* Indicates Existing Equip.	Flex Coil Interface				
meleates Existing Equip.	Loop Flex Coil, Large				
	Shoulder Array Coil				
	Invivo Avanto Knee/Foot Coil				
	Invivo Wrist Coil				
	Invivo 7 Channel Biopsy Breast Coil				
	* PA Matrix Coil (plus coil cart)				
	Syngo Inline, Phoenix, Intelligent Coil Control				
	1D/2D PACE, iPAT, BLADE, SPACE, Inline				
System Software:	Diffusion, Tim Application Suites - Neuro,				
	Angio, Cardiac, Body, Onco, Breast, Ortho,				
•	Scientific, and Pediatric				
	PMU Wireless Physio Control				
	Arm Board				
	Patient Comfort Systems Knee Wedge				
Ancillary Equipment:	Patient Music/Communication Interface				
* Indicates Existing Equip.	Mitsubishi 150kVA Power Conditioner				
	Kraus KKT KCC 215 chiller				
	* MEDRAD Spectris Solaris Power Injector				
	* MEDRAD Veris Patient Vital Signs Monitor				



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EQUIPMENT COMPARISON

	EXISTING	REPLACEMENT
	EQUIPMENT	EQUIPMENT
Type of Equipment (List Each Component)	MRI Scanner	MRI Scanner
Manufacturer of Equipment	Hitachi	Siemens
Tesla Rating for MRIs	0.3T	1.5T
Model Number	Airis II Elite	Avanto
Serial Number	11180085	26326
Provider's Method of Identifying Equipment	Serial Number	Serial Number
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	NA	NA
Mobile Tractor Serial Number/VIN #	NA	NA
Date of Acquisition of Each Component	11/21/05	To be acquired
Does Provider Hold Title to Equipment or Have a Capital Lease?	Hold title	Will hold title
Specify if Equipment Was/Is New or Used When Acquired	New	Used/Refurbished
Total Capital Cost of Project (Including Construction, etc.) <use attached="" form=""></use>	NA	\$1,332,793.82
Total Cost of Equipment	NA	\$850,000
Fair Market Value of Equipment	NA	\$850,000
Net Purchase Price of Equipment	NA	\$850,000
Locations Where Operated	Watauga Medical	Watauga Medical
	Center	Center
Number Days In Use/To Be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	NA	0%0
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0%0
Type of Procedures Currently Performed on Existing Equipment	MRI	NA
Type of Procedures New Equipment is Capable of Performing	NA	MRI

EXHIBIT "C" PROPOSED TOTAL CAPITAL COSTS OF PROJECT

	r/Company: Watauga Medical Center & King	's Medical Compan	<u>1</u> <u>Y</u>	10 NTHON
A. Site			***	
(1)	Full purchase price of land	¢0.00	\$0.00	PATH CKE
(2)	Acres Price per Acre Closing costs	\$0.00	\$0.00	CO CO
(3)	Site Inspection and Survey		\$0.00	" NCOR
(4)	Legal fees and subsoil investigation		\$0.00 \$0.00	A666666668
(5)	Site Preparation Costs		\$0.00	
(5)	Soil Borings	\$0.00		DERG-HUGHEO
	Clearing-Earthwork	\$0.00		A BLUTECTO
	Fine Grade for Slab	\$0.00		A Chillen On
	Roads-Paving	\$0.00		1818
	Concrete Sidewalks	\$0.00		CERT. NO.
	Water and Sewer	\$0.00		CERT. NO.
	Footing Excavation	\$0.00		12/12 210
	Footing Backfill	\$0.00		1 Pr.
	Termite Treatment	\$0.00		CO PANY CAROLINA
	Other (Specify)	\$0.00		CONCORD, N. G.
	Sub-Total Site Preparation Costs	+0.00	\$0.00	SANN' W
(6)	Other (Specify)		\$0.00	
(7)	Sub-Total Site Costs		φοιοσ	<u>\$0.00</u>
	struction Contract			Printer Additional of the Printer of
(8)	Cost of Materials			
` ' '	General Requirements	\$8,737.90		
	Concrete/Masonry	\$1,675.60		
	Woods/Doors & Windows/Finishes	\$11,823.98		
	Thermal & Moisture Protection	\$5,203.80		
	Equipment/Specialty Items	\$0.00		
	Mechanical/Electrical	\$26,184.55		
	Other (Specify) Plumbing/Sprinkler	\$2,732.40		
	Sub-Total Cost of Materials		\$56,358.23	
(9)	Cost of Labor		\$52,513.21	
(10)	Other (Specify) RF Shield Testing & Repair		\$15,000.00	
(11)	Sub-Total Construction Contract			\$123,871.44
C. Misc	ellaneous Project Costs			
(12)	Building Purchase		\$0.00	
(13)	Fixed Equipment Purchase/Lease		\$850,000	
(14)	Movable Equipment Purchase/Lease		\$0.00	
(15)	Furniture		\$0.00	
(16)	Landscaping		\$0.00	
(17)	Consultant Fees			
	Architect and Engineering Fees	\$25,000		
	Legal Fees	\$0.00		
	Market Analysis	\$0.00		
	Other (Specify):	\$0.00		
(1.0)	Sub-Total Consultant Fees		\$25,000	
(18)	Financing Costs for MRI purchase		\$83,922.38	
(19)	Interest During Construction		\$0.00	
(20)	Other (Specify): \$70,000 delivery, installation/de-		\$250,000	
	tion, & training. \$180,000 temp mobile MRI rent			** *** ***
(21)	Sub-Total Miscellaneous Total Capital Cost of Project (Sum A-C above)			\$1,208,922.38 \$1,333,703.83
(22)	Total Capital Cost of Project (Sum A-C above)			<u>\$1,332,793.82</u>
if s that	to the best of my knowledge, the costs of the proposed	project named abox	e are complete and co	rrect
171			-	
WM	WYULL, ATA, NC. LICEUSE 1	ND 3437	Date Certified:	12.7.12
ature of	Licensell Architect or Engineer)			
are that,	to the best of my knowledge, the above costs for the	proposed project a	re complete and corre	ect and that it is my into
out the	proposed project as described.		•	· ·
]//	4/1/201			12/10/201
the same was			Date Signed:	121101201