



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

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne
Assistant Secretary for Audit and
Health Service Regulation

April 22, 2016

Denise Gunter
Nelson Mullins Riley & Scarborough LLP
380 Knollwood Street, Suite 530
Winston-Salem, North Carolina 27103

Exempt from Review – Replacement Equipment

Record #: 1927
Business Name: Jacksonville Diagnostic Imaging, LLC
Business #: 1039
Project Description: Replace mobile MRI scanner, MQ2, with comparable mobile MRI scanner which will be known as MQ26
Counties: Mecklenburg, Gaston, Union

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of April 11, 2016, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, a mobile MRI scanner to replace the existing General Electric 1.5T Signa HD1 mobile MRI scanner, known as MQ2. Mobile MRI scanner MQ2 will be permanently fixed at Novant Health Imaging-Gastonia, Project I.D. #F-8793-12, in order to implement that project.

Moreover, you need to contact the Agency's Construction Section to determine if it has 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



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

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

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

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separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,



Gloria C. Hale
Project Analyst



Martha J. Frisone
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR
Kelli Fisk, Program Assistant, Healthcare Planning, DHSR

Nelson Mullins

Nelson Mullins Riley & Scarborough LLP

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April 11, 2016

Hand Delivered

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

Re: Notice Pursuant to N.C. Gen. Stat. § 131E-184(a)(7) of Replacement
Equipment and Implementation of CON for Project I.D. No. F-8793-12
Health Service Area III
Mecklenburg County

Dear Ms. Frisone:

Pursuant to N.C. Gen. Stat. § 131E-184(a)(7), I am writing on behalf of Jacksonville Diagnostic Imaging, LLC ("JDI") and Novant Health Imaging - Gastonia ("Gastonia"), both subsidiaries of Novant Health, Inc. ("Novant") to provide prior written notice of the acquisition of a replacement mobile MRI scanner for JDI and the implementation of an approved fixed MRI scanner at Gastonia pursuant to a Certificate of Need issued for Project I.D. No. F-8793-12. The facts supporting this request are set forth below.

JDI:

JDI proposes to replace its existing mobile MRI scanner, known internally as MQ 2. Novant will acquire a refurbished General Electric 1.5T Mobile MRI scanner and trailer, which will be known as MQ 26. An equipment comparison form is attached as Exhibit A. MQ 26 meets the requirements of both N.C. Gen. Stat. § 131E-176(22a) and 10A NCAC 14C.0303(d). The total capital cost for the project is \$835,000. This includes all costs essential to acquiring and making operational the replacement equipment. This replacement is therefore well below the \$2 million threshold in N.C. Gen. Stat. § 131E-176(22a). See Exhibit B - Project Capital Cost and Exhibit C - Equipment Quote.

Martha J. Frisone
April 11, 2016
Page 2

The total inventory of mobile MRI scanners in North Carolina will not change as a result of this project.

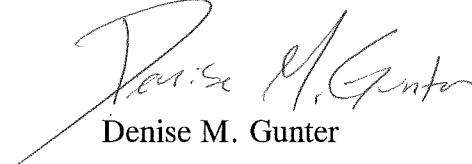
Gastonia:

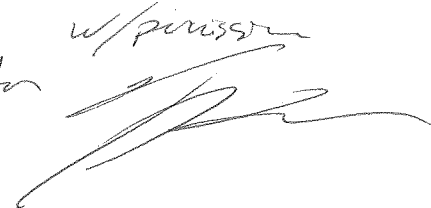
Novant was awarded a CON in Project I.D. No. F-8793-12 to acquire a fixed MRI scanner at Gastonia. As outlined in the Progress Reports for Gastonia and in discussions with the Agency, the acquisition of a fixed MRI scanner is not feasible in the current location due to construction issues with the building. As such, Novant is prepared to permanently fix a mobile MRI scanner at its existing location. Novant will do so utilizing the MQ 2 mobile unit. The MQ 2 unit will be permanently fixed to the Novant site and will not serve multiple host sites. Novant will submit a final progress report upon completion of the project. By using MQ 2, the project capital costs associated with this option will be considerably lower than originally estimated in the CON application.

Based on the foregoing, we respectfully request that the Agency confirm in writing that the JDI replacement is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7), and that Novant may utilize the MQ 2 unit as the unit that that was approved in Project I.D. No. F-8793-12.

If you have any questions, please let me know. Thank you for your time and consideration.

Sincerely,


Denise M. Gunter

w/frisone


Enclosures

EQUIPMENT COMPARISON - MRI REPLACEMENT

JDI - Project ID No. F-6626-02

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	MRI Scanner	MRI Scanner
Manufacturer of Equipment	General Electric	General Electric
Tesla Rating for MRIs	1.5T	1.5T
Model Number	Signa HDI	Echospeed
Serial Number	R2193	R380
Provider's Method of Identifying Equipment	Serial Number MQ 2	Serial Number MQ 26
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1S9FA482021182551	1JYV482W5XL512394
Mobile Tractor Serial Number/VIN #		
Date of Acquisition of Each Component	2010	2016
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	Used	Used
Total Capital Cost of Project (Including Construction, etc.) < Use Attached Form >	\$748,320	\$835,000
Total Cost of Equipment	\$748,320	\$835,000
Fair Market Value of Equipment	\$475,000	\$835,000
Net Purchase Price of Equipment	Same	Same
Locations Where Operated	Novant Health Imaging - Gastonia; NHI-Monroe, NHI-Steel Creek (Mecklenburg)	NHI-Monroe NHI-Steel Creek (Mecklenburg)
Number Days In Use/To Be Used in N.C. Per Year	365 less any holidays	365 less any holidays
Percent of Change in Patient Charges (by Procedure)	NA	NA
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	NA
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

PROJECT CAPITAL COST

A. <u>Site Costs</u>			
(1)	Full purchase price of land	\$	<u>Not Applicable</u>
	# Acres _____ Price per Acre \$ _____		
(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		
C. <u>Miscellaneous Project Costs</u>			
(12)	Building Purchase	\$	
(13)	Fixed Equipment Purchase/Lease	\$	<u>\$835,000</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)	\$	_____
	Other (specify _____)	\$	_____
(21)	Sub-Total Miscellaneous		<u>\$835,000</u>
D.	Total Capital Cost of Project (Sum A-C above)		<u>\$835,000</u>

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

Not Applicable. No construction involved in the proposed replacement equipment project.

(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)

Astorney-in-fact
(Title of officer)

Orbit Medical Technologies, Inc.

16151 Clinton Street, Harvey, IL 60426
Tel: (708) 825-1344 Fax (866) 596-7188
sales@orbitmed.com
www.orbitmed.com



Quotation

Quote #. 1441

Date. February 23, 2016

Customer. Jacksonville Diagnostic Imaging, LLC

3480 Preston Ridge Road, Alpharetta, GA 30005

Equipment Being Offered:

Refurbished GE 1.5T 23x 16-Channel CXX4 Mobile MRI System

MRI Magnet Serial Number: R380

Ellis and Watts Trailer

Model Number: TL-4865

Serial Number: 16604

VIN Number: 1JJV482W5XL512394

System Features:

- Detachable Patient Table Accommodates Patient Weight to a Maximum 350 lbs.
- HFD Gradient Driver 33 mT/m, Slew Rate 120
- High Performance Gradient Subsystem
- DICOM 3.0 Compliant

System Hardware Included:

- 1.5T Echospeed Plus 23.0X 16-Channel Electronics with Phased Array
- HP Linux Dual Processor Workstation/Operator Console w/Wide Screen
- 16- Channel Digital RF System
- VRE Reconstruction Engine

ScanTools 23.0 System Software Includes:

Modality Worklist (MWL), Flow and Volume Measurement, Bloodsupp, ConnectPro, iDrive, iDrive Pro, iDrive Pro Plus, Performed Procedure Step, Protocol Library, ProtoCopy, Workflow Manager, AutoStart, AutoScan, AutoVoice, Linking, Inline Processing, Inline Viewing and Image Fusion, FuncTools, IP Protection, 16 Channel System

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Fast Spin Echo Based Acquisitions: Fast Spin Echo (FSE), Fast Spin Echo-XL (FSE-XL), Fast Recover Fast Spin Echo (FRFSE), Single Shot Fast Spine Echo (SSFSE), FLAIR, 3DFRFSE

Gradient Echo Based Acquisitions: GRE, FGRE, SPGR, FSPGR, 2D and 3D Dual Echo Gradient Echo, 2D and 3D Time of Flight (TOF), 2D MERGE, 3D MERGE, COSMIC, 2D FIESTA, 3D FIESTA, 3D FatSat FIESTA, BRAVO, SPECIAL, LAVA, FastCINE, iDrive Pro, SmartPrep

Echo Planar Based Acquisitions: Diffusion EchoPlanar Imaging (DW EPI), FLAIR EPI, Array Spatial Sensitivity Encoding Technique (ASSET), Auto-Calibrating Reconstruction (ARC)

Propeller 3.0 Package: T1 FLAIR Propeller, T2 Propeller, T2 FLAIR Propeller, Diffusion Weighted Propeller (DW Propeller)

VIBRANT Package: Vibrant (Breast2)

IDEAL: Provides consistent, robust fat and water separation every time. Four different contrasts: water-only, fat-only, in-phase, out-of-phase are generated from a single acquisition, to help facilitate more confident diagnoses and reduce repeat exams

Additional Software Upgrades:

Inhance 2.0 Suite: Inhance 2D Inflow, Inhance 3D Velocity, Inhance 3D Inflow IR

- LAVA, LAVA-XV
- Enhanced Diffusion Weighted Imaging (eDWI)
- Time Resolved Imaging and Contrast Kinetics (TRICKS)
- Phase Contrast Vascular Imaging
- Probe Press Single Voxel
- Probe 2000 Upgrade & Probe 3D Brain
- CUBE T2
- T2 STAR WEIGHTED IMAGING (SWAN)
- Fluoro Triggered MRA
- Spectroscopy PROBE

Coil List:

- 16-Channel Head, Neck and Spine Coil
- 12-Channel Body Coil
- 8-Channel Breast Coil

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- 8-Channel T/R Knee Array
- 8-Channel Foot and Ankle Array
- 8-Channel Wrist Array
- 3-Channel Shoulder Array
- General Purpose Flex Coil

- **Medrad Spectris Soloris Dual Head Injector**

Additional Items:

Refurbished Trailer: Refurbishment of Trailer will be limited to:

Exterior:

- Test generator/ fix issues
- Paint Trailer
- Weather stripping on all doors
- Check tires replace if needed
- Refurbish patient lift
- Replace door hardware with stainless
- Fix generator corners
- Check rails
- Perform trailer checklist
- Evaluate HVAC unit fix or replacement if needed
- New Tires
- Valid DOT inspection and sticker

Interior:

- Magnet room floor ramp down and replace if necessary
- Add door stopper in magnet room
- Equipment room wall replace
- Equipment room floor replace remove system cabinets
- Equipment room ceiling remove carpet
- Install whiteboard ceiling
- Replace counter top
- Tune all cabinets all trim and wall in all three Rooms

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Quoted Price.

System Sale Price. \$835,000

Payment Terms.

- i. 30% Due upon accepting and signing the purchase agreement to effect the order and book the system
- ii. 65% Due prior of shipping the system to the customer site or within 45 days of booking the system, whichever comes first
- iii. 5% Due upon final installation at site