



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

October 3, 2017

George Sheasley
120 Williams Penn Plaza
Durham, NC 27704

Exempt from Review – Replacement Equipment

Record #: 2398
Facility Name: EmergeOrtho (formerly Triangle Orthopaedic Associates)
FID #: 040412
Business Name: EmergeOrtho
Business #: 1888
Project Description: Replace existing magnetic resonance imaging (MRI) scanner
County: Durham

Dear Mr. Sheasley:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of September 15, 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 1.5T MRI scanner to replace the existing Fonar 0.6T MRI scanner located in the Southpoint Professional Center, NC Highway 54 in Durham. 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 and Radiation Protection 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,

Bernetta Thorne-Williams
Project Analyst

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

cc: Construction Section, DHSR
Radiation Protection Section, DHSR
Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR

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



Record# 2398
Business# 1888
FID# 040412
120 William Penn Plaza
Durham, NC 27704



September 7, 2017

Ms. Martha Frisone
Chief, Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603



RE: Imaging Equipment Replacement at EmergeOrtho/Durham County
CON Project # J-8107-08

Dear Ms. Frisone:

EmergeOrtho (EO), formerly Triangle Orthopaedic Associates, intends to replace its existing Fonar multi-position fixed MRI scanner located in our Southpoint Professional Center clinic on N.C. Highway 54 in Durham. Pursuant to NCAC 14C .0303(a), EO requests confirmation that this replacement lies within the definition of NCGS 131E-176(22a) and the regulations set out in NCGS 131E-184(a)(7) and NCAC 14C .0303, as exempt from review.

EO began using its upright MRI scanner in 2009, and intends to replace it with a refurbished Siemens Aera 1.5T fixed MRI scanner. Via this letter, EO affirms that it will sell the Fonar upright MRI scanner to a third-party, for removal of the Fonar scanner from North Carolina. EO will continue to maintain an inventory of one (1) fixed MRI scanner at its Southpoint Professional Center.

Pursuant to NCGS 131E-184(a)(7) "The department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, when notice includes an explanation of why the new institutional health service is required, for any of the following: ... (7) To provide replacement equipment."

NCGS 131E-176(22a) defines “replacement equipment” as “*equipment that costs less than \$2,000,000 and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced*”.

Applicable Regulations

NCAC 14C .0303 defines “comparable medical equipment” as equipment that is functionally similar and which is used for the same diagnostic or treatment purposes. Replacement equipment is comparable if:

- (1) it has the same basic technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
- (2) it 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 12 months after replacement equipment is acquired.

Compliance

EO hereby certifies that:

1. The total project cost for the MRI scanner replacement is \$1,176,000, as shown in Attachment A. Please refer to Attachment B for the Siemens equipment quote. EO will locate the replacement MRI scanner in the existing MRI equipment room at the Southpoint clinic. EO’s General Contractor confirms that relatively modest space renovations are required to accommodate the replacement MRI scanner. The cost to remove the existing MRI scanner from EO will be borne by the third-party buyer, and Siemens is including delivery and installation costs in the sale price of the refurbished Area scanner. During the equipment replacement process, EO will temporarily contract for a mobile MRI scanner to serve the Southpoint clinic.
2. The replacement MRI scanner will be installed at EO for the sole purpose of replacing comparable equipment currently in use, which will be relocated out of state. A comparison of the existing and replacement equipment is provided in Attachment C.
3. The replacement MRI scanner is functionally similar to the existing equipment and will be used for the same diagnostic procedures as the equipment currently in use. The replacement equipment is a full-featured MRI scanner, with features that do not change the basic technology or result in the provision of a new health service or type of procedure.

4. No increase in charges will occur within the first twelve months after the replacement MRI scanner is acquired.
5. The average cost per procedure will not increase by more than 10% as a result of the replacement.

As per the Proposed 2018 State Medical Facilities Plan, the State Health Coordinating Council has ended the multi-position MRI scanner demonstration project, and has added EO's Fonar Upright MRI scanner to the standard MRI inventory for Durham County. EO requests that the Division of Health Service Regulation confirm that replacement of the fixed upright MRI scanner as proposed herein does not constitute a new institutional health service and is exempt from certificate of need review.

Please contact me at 919.281.1804 regarding any questions concerning this request.

Sincerely,



George Sheasley
Chief Financial Officer

Attachments: A - Proposed Capital Cost
B - Vendor Equipment Quote
C - Equipment Comparison

Attachment A: Proposed Capital Cost

Attachment A

PROPOSED CAPITAL COST

Project name: MRI Scanner Replacement
 Proponent: EmergeOrtho

A. Site Costs	
(1) Full purchase price of land # Acres ___ Price per acre _____	
(2) Closing costs and legal fees	
(3) Site inspection and survey	
(4) Site preparation costs	
(5) Other	
(6) Subtotal Site Costs	\$0
B. Construction Contract(s)	
(7) Cost of construction contract(s)	\$75,000
(8) Other	\$0
(9) Subtotal construction contract(s)	\$75,000
C. Miscellaneous Project Costs	
(10) Building purchase	
(11) Equipment & furniture not included above	\$975,000
(12) Consultant fees	
Architect & engineering fees	\$5,000
Certificate of need preparation	
Legal fees	
Market analysis	
Other	
Subtotal consultant fees	\$5,000
(13) Financing costs	
Bond	
HUD	
Commercial loan	
Other (specify)	
Subtotal financing costs	\$0
(14) Interest during construction	\$0
(15) Other (sales tax)	\$71,000
(15) Other (mobile MRI scanner rental)	\$50,000
(16) Subtotal miscellaneous project costs	\$126,000
Total Capital Cost of Project	\$1,176,000

Attachment B: Vendor Equipment Quote

Subject:

FW: Attention George. Nationwide Imaging Follow Up. Fonar.

2010 SIEMENS AERA 1.5T TIM PLUS DOT MRI
SYNGO MR E11, VE11A
XJ-GRADIENTS, 33 MTM, SR 125
48 RF CHANNELS
TIM 204 X 48
OR 98 MAGNET
SUMMITOMO COLDHEAD AND COMPRESSOR
TIM APPLICATION SUITE
ANGIO SUITE
CARDIAC SUITE
NEURO SUITE
BODY SUITE
ONCO SUITE
ORTHO SUITE
QUIET SUITE
BREAST SUITE
SCIENTIFIC SUITE
SYNGO GENERAL
3D USAGE
3D MPR
3D SSD
3D MIP
3D SSD
ARGUS VIEWER
WORKLIST
PHOENIX ZIP
CISS AND DESS
TIM CT FAST VIEW
I PAT EXTENSIONS
MOTION CORRECTION
IMAGE FILTER
MPPS
INLINE 3D DISTORTION CORRECTION
3D DISTORTION CORRECTION
MDDW
MORPHE QUALITY CONTROL
INLINE DIFFUSION
BLADE
TGSE
DOT ENGINE BASIC

BRAIN DOT ENGINE
AUTO ALIGN HEAD
SPECTROSCOPY SVS
FLOW QUANTIFICATION
SPECTROSCOPY 2D CSI
MR SPECTROSCOPY EVALUATION
COMPOSING
INLINE PERFUSION
INLINE COMPOSING
DIFFUSION TENSOR IMAGING
TIM PLANNING SUITE
SWI
TWIST
NATIVE
2D ASL
SPECTROSCOPY 3D CSI
IMAGE MANAGEMENT
NEURO PERFUSION LOCAL A/F
FAST DICOM
Q-SPACE
TQSE
FLOW QUANT
SPEC POST PROC
PAT ADVANCED
DYNAMIC 3D
ARTERIAL SPIN LABELLING
STEREOTATIC TSE
48 CHANNEL
MR ARGUS MAIN
CAP 3D FLY MODE
MR ARGUS FLOW ANALYSIS
MR SPEC POST PROCESS
SYNGO GENERAL
FILM VFS
CAP3D MAIN
CAP 3D VOI MODE
CAP 3D FILTER SSD
CAP 3D FILTER MIP
CAP 3D FILTER VRT
CAP 3D EDITOR
CAP 3D FUSION BASE
CAP 3D FUSION LM
CAP 3D FUSION AUTO
CAP 3D FUSION LAYOUT
CAP 3D FUSION CLIP VIEW
CAP 3D ROTATING OMIP
DICOM SR VIEWER
DIFFUSION TENSOR
REMOTTE DESKTOP
CAP 3D MULTI MONITOR

CAP 3D BONE REMOVAL
GEN MAIN
IVT ADVANCED RENDERING
3D DIFFUSION TRACTS
SYNGO VIA READY
COILS:
HEAD NECK 20
SPINE 32 CH
BODY 18CH
HAND/WRIST
FOOT /ANKLE
SHOULDER LARGE SHOULDER SMALL
TIM COIL INTERFACE
FLEX COIL INTERFACE
4 CH FLEX LARGE
4CH FLEX SMALL
4CH BREAST
15 CH KNEE
PHANTOMS

PRICE: \$975,000.00

THIS PRICE INCLUDES DELIVERY, INSTALLATION AND A 1 YEAR SERVICE AGREEMENT

Attachment C: Equipment Comparison

Attachment C

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	MRI Scanner	MRI Scanner
Manufacturer of Equipment	Fonar	Siemens
Tesla Rating of MRIs	0.6T	1.5T
Model Number	Upright	Aera
Serial Number	1412	
Provider's Method of Identifying Equipment	MRI #1	MRI #1
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN#	NA	NA
Mobile Trailer Serial Number/VIN#	NA	NA
Date of Acquisition of Each Component	2008	Target Fall 2017
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	
Specify if Equipment Was/Is New or Used When Acquired	New	Refurbished
Total Capital Cost of Project (Including Construction, etc.)		\$1,176,000
Total Cost of Equipment		\$975,000
Fair Market Value of Equipment	\$100,000	
Net Purchase Price of Equipment	\$2,381,107	\$975,000
Locations Where Operated	Durham, NC	Durham, NC
Number Day in Use/To be Used in NC per Year	365	365
Percent of Change in Patient Charges (by Procedure)	NA	No increase
%Change in per Procedure Operating Expenses (by Procedure)	NA	No increase
Type of Procedures Currently Performed on Existing Equipment	High Resolution Imaging	NA
Type of Procedures New Equipment is Capable of Performing	NA	High Res.Imaging