

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor KODY H. KINSLEY • Secretary MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

August 22, 2022

Conor Brockett Conor.brockett@emergeortho.com

Exempt from Review – Replacement Equipment		
Record #:	4005	
Date of Request:	August 8, 2022	
Facility Name:	EmergeOrtho	
FID #:	040412	
Business Name:	EmergeOrtho, P.A.	
Business #:	2716	
Project Description:	Replace existing mobile MRI scanner and trailer	
County:	Burke, Caldwell, and Catawba	

Dear Mr. Brockett:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project 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 the GE Signa HDxt (23x) 1.5T mobile MRI scanner to replace the GE 12HD 1.5T (serial # R1776). 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.

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,

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Ena Lightbourne Project Analyst

Micheala Mitchell Chief

> 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



August 5, 2022

Via E-mail

Micheala Mitchell, Chief Healthcare Planning and Certificate of Need Section N.C. Department of Health and Human Services Division of Health Service Regulation 2704 Mail Service Center Raleigh, NC 27699-2704 micheala.mitchell@dhhs.nc.gov

Re: EmergeOrtho's Notice of Exemption from Review for Replacement of Mobile MRI Scanner (serving Catawba, Caldwell, and Burke Counties) and Trailer

Dear Ms. Mitchell,

EmergeOrtho, P.A. ("EO") owns and operates a mobile MRI scanner (Project ID E-8230-08) serving locations in Catawba, Burke, and Caldwell Counties. Due to the age of the unit, lessening reliability, and increasing maintenance costs, it is now necessary to replace both the scanner and the trailer/coach.

I write to provide advance notice to the N.C. Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "CON Section") of EO's planned acquisition of replacement equipment, and to request written confirmation from the CON Section that the replacement of our MRI scanner and trailer is exempt from CON review pursuant to N.C. Gen. Stat. §131E-184(a)(7).

Regulatory Framework

North Carolina's CON Law prohibits any person from offering or developing a "new institutional health service" without first obtaining a certificate of need. N.C.G.S. § 131E-178(a). The definition of "new institutional health service" includes the following:

- The acquisition by purchase, donation, lease, transfer, or comparable arrangement of major medical equipment. See G.S. §131E-176(16)p.
- The acquisition by purchase, donation lease, transfer, or comparable arrangement of an MRI scanner, regardless of cost. See G.S. §131E-176(16)f1.7.

However, G.S. 131E-184(a)(7) provides an express exemption from CON review for the acquisition and installation of "replacement equipment" costing less than \$2,000,000, so long as the CON Section receives prior written notice from the proposing party explaining why the acquisition and installation is required and qualifies for the exemption.

Ms. Mitchell Exemption Notice EmergeOrtho MRI Scanner August 5, 2022

The CON Law further defines "replacement equipment" as:

Equipment that costs less than two million dollars (\$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. In determining whether the replacement equipment costs less than two million dollars (\$2,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

G.S. §131E-176(22a). CON Section administrative rule further instructs that replacement equipment is "comparable" to the existing equipment if:

- (1) it has the same 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 twelve months after the replacement equipment is acquired.

10A N.C.A.C. 14C .0303(d).

Project Description

EO's existing mobile MRI scanner is a GE 12HD Mobile 1.5T, serial number R1776, which was acquired by a predecessor entity¹ in 2009. The scanner is housed and operated in a mobile trailer/coach, which was acquired with the scanner in 2009. EO intends to replace both the scanner and trailer in this project.

The 2009 scanner has limited technological capabilities; a primary one being that it cannot easily interface with newer practice management applications. The scanner also requires maintenance more frequently, and replacement parts are becoming difficult to source. When parts are available, they are very expensive. EO has also been informed that the manufacturer will soon discontinue servicing and supporting the unit, which would create operational and security risks with continued

¹ Carolina Orthopaedic Specialists, P.A. ("COS") received the original CON for this MRI scanner. Ownership of the scanner was transferred to EmergeOrtho when COS affiliated/merged with EO in 2016.

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use. The trailer that houses the scanner is also in need of replacement from 12 years of regular and consistent use.

The proposed replacement scanner is a GE Signa HDxt (23x) 1.5T, which EO anticipates will be delivered by December 1, 2022. The estimated cost is \$474,353.65. A new Ellis & Watts trailer to house and transport the proposed replacement unit is estimated to cost \$200,000. Please refer to Exhibit A for additional specification details of the replacement equipment.

Meeting the Exemption

The replacement of EO's mobile MRI scanner and trailer is within the parameters of the statutory exemption based on the following information:

- 1. The equipment being replaced is currently in use by EmergeOrtho in Catawba, Caldwell, and Burke Counties pursuant to a Certificate of Need issued in 2009.
- 2. The total estimated cost to acquire and install the replacement MRI scanner and trailer is less than \$2,000,000, placing the project within the statutory exception. The total estimated cost is based on the following quotations:

GE Signa HDxt Scanner	\$474,353.65
Ellis & Watts Trailer	\$200,000.00
Total	\$674,353.65

- 3. The MRI scanner currently in use will be removed upon acquisition and installation of the replacement MRI scanner, disposed of by the seller of the replacement scanner, and no longer used in North Carolina.
- 4. The replacement MRI scanner will have the same capabilities as the scanner being replaced, although it may have some additional capabilities due to technological advances. It is also functionally similar to the unit currently in use and will be used for the same diagnostic and treatment purposes, and in accordance with the 2009 CON.
- 5. EO is not acquiring any other new major medical equipment or offering any new institutional health services in this equipment replacement project.
- 6. The project will not result in an increase in patient charges or per procedure operating expenses in the first twelve months after acquiring the replacement equipment.

Ms. Mitchell Exemption Notice EmergeOrtho MRI Scanner August 5, 2022

Conclusion

We believe the proposed replacement of EO's existing MRI scanner is exempt from review by the CON Section and that no CON is required for this project. We would request your written confirmation of this position following your review of the provided documentation.

Thank you for your review and consideration of this information. Please contact me at (919) 809-2514 or conor.brockett@emergeortho.com if you have any questions.

Sincerely,

Conor Brockett

Conor Brockett General Counsel

<u>Exhibit A</u>



Presented To: EmergeOrtho





PURCHASE AGREEMENT

This Purchase Agreement ("Agreement") dates as of July 29, 2022 is made by and between MXR Imaging, Inc. ("SELLER"), located at 8020 Tyler Blvd, Mentor, OH 44060, and EmergeOrtho ("PURCHASER"), having its principal place of business located at PO BOX 999, Hiickory, NC 28603 PURCHASER hereby agrees to purchase the Equipment described in APPENDIX A ("Equipment") in accordance with the terms and conditions set forth below in this Agreement and the standard terms and conditions set forth herein and incorporated to this Agreement by reference:

PURCHASE PRICE

The PURCHASER agrees to pay SELLER \$674 353.65, and any applicable taxes, as well as any other amounts payable under this Agreement ("Purchase Price"). Payments shall be made in U.S. Dollars. SELLER will take ownership of a GE 12HD Mobile, currently in PURCHASER'S possession as a trade in with a value of \$150,000.00. PURCHASER must provide an original, clear title for the GE 12HD Mobile.

EQUIPMENT DESCRIPTION

Warranty

*Equipment is available at the time the Agreement was created but could be sold to another purchaser. If this occurs MXR will notify PURCHASER

DELIVERY LOCATION & DATE

SELLER agrees to deliver the Equipment to EmergeOrtho, located at 841 Malcolm Boulevard, Rutherford College, NC, 28671, on or about November 30, 2022

CLINICAL APPLIATIONS TRAINING

SELLER will provide 4 days applications training upon completion of installation.

EXECUTION OF AGREEMENT AND DEPOSIT

PURCHASER shall return an executed Agreement to SELLER on or before July 29, 2022, along with a deposit of 30.00%, \$157,306.10 via certified company check or bank wire transfer for the Equipment outlined in Exhibit A.

- 1. PURCHASER is responsible for any bank wire fees. If for any reason a check is returned for insufficient funds, there will be a charge of \$150.00 per returned check. If in the event the contract is cancelled or null and void, this fee still applies.
- 2. SELLER has the right to re-quote the purchase price if not signed on or before the date specified.

PAYMENT TERMS

The remaining balance of \$367,047.56 after payment of deposit is to be due as follows;

- 60.00%, \$314,612.19 due 3 days prior to shipment to site
- 10.00%, \$52,435.37 due upon completion of installation



Purchase Agreement NIS-001717

1113-001717

EQUIPMENT LIST EXHIBIT "A"

CERTIFIED PLATINUM GE Signa 1.5T 23X-MXR104951

CERTIFIED PLATINUM E&W MOBILE WITH NORTHEN AIR CONDITIONERS MXR104911

SOFTWARE LEVEL: HD23.0_1406A

LICENSE OPTIONS:

- ARC
- ASSET
- **BLOOD FLOW AND VOLUME MEASUREMENTS**
- BLOOD SUPP
- BRAVO
- CINE
- COSMIC
- 3D DUAL ECHO
- DW EPI
- E3DTOF
- ENHANCED DWI
- ECHO PLANAR IMAGING
- FAST CINE
- FAST GRADIENT ECHO
- FIESTA 2D
- 2D FAT SAT FIESTA
- S FIESTA 3D
- 3D FAT SAT FIESTA
- FIESTA C
- FLAIR EPI
- 3DFRFSE
- FAST SPIN ECHO AND FLAIR
- FSE XL
- FLUORO TRIGGERED MRA
- TIME OF FLIGHT
- MODALITY WORKLIST
- IDRIVE
- IDRIVE PRO
- INHANCE DELTA FLOW
- INHANCE 2D INFLOW
- INHANCE 3D VELOCITY
- INHANCE 3D INFLOW IR
- LAVA
- LAVA DE
- LAVA XV
- 2D MERGE
- 3D MERGE
- MULTI-PHASE (VARIABLE DELAYS)
- PHASE CONTRAST VASCULAR IMAGING
- PROBE 2000 UPGRADE
- PROBE PRESS
- PROPELLER
- DW PROPELLER

CUST. INT.

Kr

MXR INT.



Purchase Agreement

NIS-001717

- T1 FLAIR PROPELLER
- T2 PROPELLER
- T2 FLAIR PROPELLER
- PROBE 3D PROSTATE
- QUICK STEP
- IDRIVE PRO PLUS
- SMART PREP
- SPECIAL
- SSFSE
- SSFSE MRCP
- THREE PLANE LOCALIZER
- TRICKS
- IP PROTECTION
- 16 CHANNEL

COILS:

- 1. HD HNS 16 CH
- 2. TORSO ARRAY
- 3. 12CH BODY ARRAY
- 4. HD T/R KNEE
- 5. MARK 9000 PHASED ARRAY SHOULDER COIL
- 6. HD 8CH WRIST ARRAY
- 7. QUAD HEAD COIL
- 8. QUAD EXTREMITY
- 9. GP FLEX COIL

Delivery to: 841 Malcolm Boulevard, Rutherford College, NC, 28671 Condition: Platinum Certified Applications Training: 4 Days Warranty: 12 Months

CUST, INT.



MXR INT.

From:	Conor Brockett
То:	<u>Waller, Martha K</u>
Cc:	Conor Brockett
Subject:	[External] Fwd: EmergeOrtho Notice of Exemption of Review (Mobile MRI)
Date:	Monday, August 8, 2022 4:43:18 PM
Attachments:	EmergeOrtho Ltr to CON Section re MRI Replacement, 2022-08-05.pdf
	Exhibit A, MXR Quote for Scanner and Trailer (1).pdf

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to <u>Report Spam.</u>

Ms. Waller,

Thank you for the guidance today. I am forwarding to you my message to Ms. Mitchell with attachments as submitted on Friday.

Conor Brockett | General Counsel & Chief Compliance Officer EmergeOrtho Phone: +1 (919) 281-1702 | Fax: +1 (919) 281-0371 conor.brockett@emergeortho.com | www.EmergeOrtho.com



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Begin forwarded message:

From: Conor Brockett <conor.brockett@emergeortho.com> Date: August 5, 2022 at 1:38:58 PM EDT To: micheala.mitchell@dhhs.nc.gov Cc: Conor Brockett <conor.brockett@emergeortho.com> Subject: EmergeOrtho Notice of Exemption of Review (Mobile MRI)

Ms. Mitchell, good afternoon.

Please find attached a letter and supporting documents from EmergeOrtho, P.A., which seeks confirmation that EmergeOrtho's plan to replace its current, aging mobile MRI scanner and trailer in the Foothills region of North Carolina is exempt from CON review. Thank you for your consideration of this filing. I would appreciate your confirmation of receipt of these materials, and would also invite you to contact me at (919) 809-2514 to discuss any details or question you or your colleagues may have about this.