

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

October 3, 2024

April Culver

april.culver@unchealth.unc.edu

Exempt from Review - Replacement Equipment

Record #: 4589

Date of Request: September 30, 2024

Facility Name: UNC Health Johnston – Clayton Campus

FID #: 061348

Business Name: Johnston Memorial Hospital Corporation

Business #: 1052

Project Description: Temporary replacement of MRI scanner

County: Johnston

Dear Ms. Culver:

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 Siemens mobile MRI scanner (Serial #30799) to temporarily replace the fixed MRI scanner. This determination is based on your representations that the existing MRI scanner unit will be repaired and placed back into service, after which the lease agreement for the temporary mobile MRI scanner will be terminated, and the leased mobile MRI scanner will be removed from the facility.

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,

Cynthia Bradford Project Analyst

Micheala Mitchell

Micheala Mitroell

Chief

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION



September 30, 2024

VIA ELECTRONIC MAIL

Ms. Micheala Mitchell, Chief
Ms. Cynthia Bradford, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation, NCDHHS
2704 Mail Service Center
Raleigh, NC 27699-2704
Micheala.Mitchell@dhhs.nc.gov
cynthia.bradford@dhhs.nc.gov

RE: Notice for Exemption from CON Review for Temporary Replacement of MRI Scanner

Facility: UNC Health Johnston-Clayton

FID #: 943290

Dear Ms. Bradford:

Pursuant to NC General Statute § 131E-184(a)7, please accept this letter as notification of UNC Health-Clayton's intent to utilize a vendor owned mobile MRI scanner as an immediate temporary replacement for an interim period of approximately 3 weeks while its existing hospital based fixed MRI scanner (CON Project ID #J-7900-07) is undergoing repairs. The relevant Loan Agreement from Siemens has been attached for your reference.

UNC Health Johnston-Clayton currently operates a single Siemens Magnetom Espree MRI scanner to support a community hospital that serves Johnston County and beyond and requests use of the temporary unit in order to continue providing effective patient care. Once the repairs to the existing MRI scanner have been complete, the temporary mobile MRI will be taken off site and will not be used again at UNC Health-Clayton.

The temporary mobile MRI scanner, (Siemens Mobile Magnetom Espree 1.5T, serial # 30799) is comparable to the existing MRI currently in use at UNC Health Johnston-Clayton and will be used for the same diagnostic purposes as the existing equipment. The temporary mobile MRI from Siemens will not be used to provide a new institutional health service and at no time will UNC Health Johnston-Clayton operate more than one MRI scanner without obtaining any necessary regulatory approval from the Health Care Planning and Certificate of Need Section.

Based on the information provided, UNC Health Johnston-Clayton requests that the Agency provide a written response confirming that UNC Health Johnston-Clayton may operate the temporary mobile MRI

scanner furnished by Siemens without CON review. Should the Agency need additional information, please let us know as soon as possible.

Sincerely,

Tracey Carson, MHA, BSN, RN

Vice President, Clinical Operations

UNC Health Johnston

SHORT-TERM EQUIPMENT LOAN AGREEMENT

THIS SHORT-TERM EQUIPMENT LOAN AGREEMENT is made as of the 2nd day of October 2024 (the "Effective Date") by and between **Siemens Medical Solutions USA, Inc.**, a Delaware corporation with an address at 40 Liberty Blvd, Malvern, PA 19355 ("Siemens") and Johnson Medical Center Clayton with an address at 2138 HWY 42 West, Clayton, NC 27520 ("Customer").

WITNESSETH:

WHEREAS, Siemens is in the business of developing and selling various types of medical equipment, including hardware and/or software; and

WHEREAS, Siemens desires to loan certain equipment to Customer on a short-term basis, for the purpose set forth in Section 2 hereof;

NOW, THEREFORE, in consideration of the above premises and the mutual covenants contained herein, the parties hereto agree as follows:

- 1. <u>Loan of Equipment</u>. Siemens agrees to make available on a trial basis to the Customer the equipment described on Exhibit A attached hereto and made a part hereof (the "Loaned Equipment") for the period set forth in Section 8 hereof. In the event that the Loaned Equipment uses applications software, the Customer shall be entitled to use such software for the term hereof, subject to Siemens' normal software license terms and conditions, a copy of which is attached to the Quotation or is otherwise available from Siemens upon request. This bailment is one at will.
- 2. <u>Purpose of Loan</u>. Siemens agrees to make the Loaned Equipment available to the Customer for the reason or purpose selected below (select one). This Agreement may not be used to loan products for Collaboration (i.e., research) purposes.

X Customer-owned product under repair
Customer product on backorder
☐ Other

- **Transaction Information.** Completion of (a), (b), (c) and (d) required.
 - (a) Equipment ship-to entity name and address:

	Johnson Medical Center
Customer	Clayton
Street	2138 HWY 42 West
City	Clayton

State	NC
Zip code	27520
Attn	
Business #	
Cell#	

(b) Customer Contact (Authorizing Contact)

Name	Laura Murphy
Title	Radiology Manager
Office #	
Cell #	540-819-3619
	laura.murphy2@unchealth.unc.edu
Email Address	

(c) Customer Contact (Second or Backup Contact)

Name	
Title	
cell#	
Fax #	
Email Address	

(d) Siemens Contact (local RSM)

Name	Josh Wooten
	Regional Service Manager
Title	
cell#	(984)-304-3435
Fax #	
Email Address	Josh.wooten@siemens-healthineers.com

4. <u>Title, Delivery and Installation</u>.

(a) Title to the Loaned Equipment shall be and at all times remain with Siemens, but risk of loss shall pass to Customer upon delivery and remain with Customer until Siemens begins de-installation of the Loaned Equipment. Customer shall maintain adequate liability insurance with respect to its use of the Loaned Equipment. Customer shall also insure the Loaned Equipment against all common risks (i.e., fire, flood, theft, acts of God, etc.) at its own expense and for the full replacement value of the Loaned Equipment as shown in Exhibit A; this insurance shall name Siemens as the loss payee. At

the request of Siemens, Customer shall provide Siemens with an insurance certificate evidencing such insurance coverage.

- (b) The delivery of the Loaned Equipment to the installation site, and the installation, de-installation and return of the Loaned Equipment to Siemens shall be completed by Siemens, at its expense. Notwithstanding the foregoing, Siemens shall not have any responsibility for pre-installation preparations or post-removal restorations or any costs and expenses thereof.
- (c) Customer shall be solely responsible for obtaining and maintaining any and all licenses and other consents and approvals (ACR testing, Joint Commission and/or physicist testing for example) which may be required for the use and/or operation of the Loaned Equipment at its facility. Customer shall also be responsible for complying with any relevant radiation protection regulations, where applicable.
- (d) Customer (i) authorizes Siemens to file (and Customer shall promptly execute, if requested by Siemens) and (ii) irrevocably appoints Siemens its agent and attorney-in-fact to execute in the name of Customer and file, with such authorities and at such locations as Siemens may deem appropriate, any Uniform Commercial Code financing statements confirming Siemens' ownership interest with respect to the Loaned Equipment.
- (e) Customer acknowledges that Siemens may from time to time inquire in writing as to status of Loaned Product. Customer agrees to truthfully and promptly respond to these inquires in writing, and permit Siemens at reasonable times and upon advance notice to enter onto the premises of the Customer to inspect the Loaned Equipment.
- **5.** <u>Use of Loaned Equipment</u>. For the term of this Agreement, Customer shall be entitled to use the Loaned Equipment for its intended purpose. Customer agrees that:
- (a) It will use the Loaned Equipment in the proper manner and with appropriate care, pursuant to any instructions, training and manuals provided to Customer by Siemens, and solely for the purposes set forth in Section 2 hereof.
- (b) It will immediately report to Siemens or its designee any malfunction or defect, whatever the nature or cause.
- (c) It will ensure that any necessary repair, modification or service is carried out by Siemens. Siemens agrees to use its best efforts to repair the Loaned Equipment as needed in a prompt and timely fashion, following a reported malfunction.
- (d) It will not move the Loaned Equipment from the original installation site.
- (e) Upon expiration or termination of this Agreement, it will return the Loaned Equipment to Siemens, in the same condition as when delivered to Customer

(ordinary wear and tear excepted), with all patient information, including but not limited to protected health information (or "PHI", as defined in the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA") deleted or otherwise removed therefrom, except as otherwise provided in Section 10 hereof. Customer shall complete and sign the Release form attached hereto (Section B) prior to the return of the Loaned Equipment to Siemens.

- (f) It will prevent unauthorized persons from gaining knowledge of the design of the Loaned Equipment and any of its features.
- (g) It will use the Loaned Equipment only for applications that have been cleared by the FDA.
- (h) It will use the Loaned Equipment in accordance with all applicable laws, rules and regulations.
- (i) As a member of AdvaMed, Siemens encourages ethical business practices and socially responsible industry conduct and does not use any unlawful inducement in order to sell, lease, recommend, or arrange for the sale, lease, or prescription of, their products. In this regard, Customer agrees that it will use the Loaned Equipment in accordance with the United States Department of Health and Human Service's (HSS) Office of Inspector General's (OIG) published compliance guidance, which establishes a framework for appropriate business practices and interactions between health care professionals and medical device and technology manufacturers and distributors.
- 6. Liability and Indemnification. Customer shall be liable for all injuries to persons using or being examined with the Loaned Equipment, and for all damages to the Loaned Equipment and any other real or tangible personal property, and shall indemnify, defend, protect and hold harmless Siemens from any claim or action arising therefrom, if and to the extent that such injury or damage is the result of the negligent acts or omissions of Customer, its officers, employees, agents, or third parties for which it is responsible. Siemens shall be liable for all injuries to persons using or being examined with the Loaned Equipment, and for all damages to the Loaned Equipment and any other real or tangible personal property, and shall indemnify, defend, protect and hold harmless Customer from any claim or action arising therefrom, if and to the extent that such injury or damage is the result of the negligent acts or omissions of Siemens, its officers, employees, agents, or third parties for which it is responsible. **NEITHER PARTY SHALL BE LIABLE FOR ANY** LOST PROFITS, LOSS OF USE, LOST DATA OR FOR ANY SPECIAL, CONSEQUENTIAL, UNFORESEEN OR **INCIDENTIAL** DAMAGES, REGARDLESS OF THE FORM OF ACTION.
- 7. <u>Confidentiality</u>. During the term of this Agreement, the Customer agrees to protect all confidential and proprietary information (Confidential Information) of Siemens and to use its best efforts to maintain this level of confidentiality. In addition, the Customer agrees to (i) hold in strictest confidence and not disclose, release or disseminate to third parties, without the prior written consent of Siemens, all Confidential Information; (ii) use such Confidential Information only for the purposes set forth in this Agreement,

and for no other purposes whatsoever, except without the prior written consent of Siemens; and (iii) return such Confidential Information (and all copies thereof) to Siemens within thirty (30) days of receipt of a written request thereof from Siemens, but in any event no later than thirty (30) days after expiration or other termination of this Agreement.

8. Term of Agreement (Loan Period); Termination. If Loaned Equipment requires calibration by Siemens' personnel, the Loan Period will commence on the date that Siemens' personnel completes on-site calibration. Otherwise, the Loan Period will commence on the Effective Date. The Loan Period shall end on or about October 25th 2024. Either party may terminate prematurely for cause upon five (5) days prior written notice of the intended termination. The maximum term of this Agreement is sixty (60) days from date of delivery, except that the term may be unilaterally extended by Siemens (upon approval of Siemens' Compliance Office) with written notice of such extension to the Customer explaining the reason for the extension. Siemens may be required to report the fair market value of any loan extensions provided in connection with this Agreement, and such information may be made public depending on applicable federal and/or state law.



- **9.** Amendments. Any modifications of and amendments to this Agreement shall not be binding unless agreed to in writing by both parties.
- 10. <u>Notices</u>. Whenever, under the terms of the Agreement, written notice is required or permitted to be given, such notice shall be deemed to have been sufficiently given and effective when deposited in the United States Mail, in a properly stamped envelope, certified or registered mail, return receipt requested, delivered personally, sent via overnight courier, or sent via facsimile (with written confirmation of receipt) addressed to:

To Siemens: Siemens Medical Solutions USA, Inc.

221 Gregson Drive Cary, NC 27511

Attn: Michael Parrella Facsimile no: 315-655-5945

With copy to: Siemens Medical Solutions USA, Inc.

40 Liberty Blvd. Malvern, PA 19355 Attn: General Counsel Facsimile no.: 610-219-6462

To Customer: Johnson Medical Center

2138 HWY 42 West Clayton, NC 27520

- 11. <u>Force Majeure</u>. Siemens will not be liable to Customer for any failure to fulfill its obligations under this Agreement due to causes beyond its reasonable control including, without limitation, governmental laws and regulations, Acts of God or the public, war, civil commotion, blockades, embargoes, calamities, floods, fires, earthquakes, explosions, storms, strikes, lockouts, labor disputes, or unavailability of labor, raw materials, power or supplies.
- **12.** <u>Assignment.</u> Customer may not assign, sell, transfer, encumber, mortgage, hypothecate or sublease the Loaned Equipment or any interest this Agreement.
- 13. <u>Counterparts</u>. This Agreement may be executed in counterparts, each of which shall be deemed an original, but together which constitute one and the same agreement.
- 14. <u>Entire Agreement</u>. This Agreement, along with the attachments hereto, constitutes the entire agreement with the parties with respect to the subject matter hereof, and supersedes all prior and contemporaneous communications, writing or agreements.

IN WITNESS WHEREOF, the parties hereto have hereunto set their hands and seals as of the date first set forth above.

SIEMENS MEDICAL SOLUTIONS USA, IN	C. Johnson Medical Center
By:Signature	By: <mark>Signature</mark>
Print Name & Title	Print Name & Title
Date	<mark>Date</mark>

EXHIBIT A

Description of Loaned Equipment:

Quotation #_	1025	Rev#	2				
Siemens Mobil	le Magnetom E	spree 1.5t l	MRI Scanner	serial #30799			
Siemens FL# 4	<u>:00-622907 - S</u>	iemens Silv	ver contract -	PCP Monday to	Friday	8 AM to	22PM
2009 OshKos	h trailer ID A	SAM-23	VIN 1S9FA	48269118208	0		
Market value	\$975,000,00						

Current Software level VB19B

Software options:

Lic Inline 3D Distortion Correction Lic. 3D Distortion Correction

Lic. BLADE

Lic. Inline Composing

Lic. Optimized Protocols for EC

Lic. SWI

Lic. Tim Planing Suite

Lic. Tissue Motion Correction key Lic.MR Neuro Perfu. Eval. Protocols

License 3D MIP License 3D MPR License 3D SSD License 3D Usage

License Advanced Funktional Neuro

SIScense Argus Flow License Argus Main License CISS / DESS License Dynamic3D License Flow Quantification

License I-Class
License Image Filter

License Image Fusion Automatic License Image Fusion Basic License Image Fusion LM License Inline Diffusion License Inline Perfusion

License MAGNETOM Espree License MPPS

License MR Neuro Perfusion Evaluat.

License MR Spectroscopy Evaluation

License Matrix Mode License Native License ParametricMap

License PhoenixZIP

License Spectroscopy 3D CSI License Spectroscopy CSI License Spectroscopy SVS License Spine Composing License Spine Composing License Support-i - Key License Syngo General License T-Class

License T-Class
License Tim (32x8)
License Tim (76x18)
License Tim Application Suite

License Tim Whole Body License TimCT Fast View License Worklist

License Worklist
License Z Engine
License iPAT plus
License syngo WARP

Coils:

Shoulder array small
Shoulder array large
CP Extremity coil
Head Matrix Coil
Neck Matrix coil
Body Matrix Coil
4 Channel Flex coil large
4 Channel coil interface
4 Channel Flex coil small

trailer is not equipped with patient gurney

Other peripheral Model Serial number

Eaton Line Conditioner FL#400-626823	PW 9390-160	EC163CBA03
Powerware Host UPS	PW9130 3000VA	GH223A0831
MedRad Spectris Solaris Injector FL# 400-626668	3015724	10097
***SIEMENS DOES NOT SUPPLY SYRINGES,catalog		
# for syringes - SSQK 65/115VS MedRad - 800-633-		
7237.		



Section B – Post–Loan Release for Pick up/Removal of Images/Studies

<u>DO NOT SIGN UNTIL LOANED EQUIPMENT IS READY TO BE RETURNED</u> <u>TO SIEMENS</u>

Post-Loan: This acknowledgment is to be signed by the Customer prior to pick-up of the Loaned Equipment. If PHI remains on system, additional charges may apply.

At the end of the loan period, please complete the following acknowledgment prior to releasing the loaned equipment to Siemens' contracted personnel for pick up:

- All Biohazards, sharps, soiled linens etc. must be removed from trailer prior to departure
- All patient studies (PHI) have been removed from the Hard Drive of the equipment

	Johnson Medical Center	
Printed Name and Title:		
Date:		

From: <u>Mitchell, Micheala L</u>

To: "Kim Meymandi"; Bradford, Cynthia L

Cc: Waller, Martha K

Subject: RE: [External] UNC Johnston Temporary MRI Replacement Exemption

Date: Monday, September 30, 2024 10:14:56 AM

Attachments: <u>image001.png</u>

Received!

It's heartbreaking to see the images coming out of the Western part of the state. I hope you and your family fared well during the storm.

Thanks,

Micheala Mitchell, JD

NC Department of Health and Human Services

Division of Health Service Regulation

Section Chief, Healthcare Planning and CON Section

809 Ruggles Drive, Edgerton Building

2704 Mail Service Center Raleigh, NC 27699-2704

Office: 919 855 3879

Micheala.Mitchell@dhhs.nc.gov

From: Kim Meymandi < KimMeymandi@ascendient.com>

Sent: Friday, September 27, 2024 5:13 PM

To: Mitchell, Micheala L < Micheala. Mitchell@dhhs.nc.gov>; Bradford, Cynthia L

<cynthia.bradford@dhhs.nc.gov>

Cc: Waller, Martha K <martha.waller@dhhs.nc.gov>

Subject: [External] UNC Johnston Temporary MRI Replacement Exemption

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Happy Friday!

Hope you all and your families have stayed safe and dry throughout the storms today. Attached is an exemption request from UNC Health Johnston. I know it is late on Friday but when you get a chance can you please confirm receipt?

Thank you so much and I hope you have a great weekend.

Kim

Kim Meymandi | Senior consultant

<u>kimmeymandi@ascendient.com</u> | 919.226.1712 | <u>linkedin</u> | <u>www.ascendient.com</u>



Our Higher Thinking here

Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.