

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

March 21, 2024

Marcus C. Hewitt

MHewitt@Faxrothschild.com

Exempt from Review - Replacement Equipment

Record #: 4384

Date of Request: March 7, 2024 Facility Name: Rayus Radiology

FID #: 180563

Business Name: InSight Health Corp.

Business #: 2961

Project Description: Replace a mobile PET/CT scanner

County: Caldwell

Dear Mr. Hewitt:

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 United 550i 230068 mobile PET/CT scanner to replace the Siemens Horizon S1390S mobile PET/CT scanner. 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,

Cynthia Bradford Project Analyst

Micheala Mitchell Chief

cc: Radiation Protection Section, DHSR

Micheala Mitchell

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

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MARCUS C. HEWITT Direct No: 919.755.8776 Email: MHewitt@Foxrothschild.com

March 6, 2024

VIA EMAIL (micheala.mitchell@dhhs.nc.gov)

Michaela Mitchell, Chief N.C. Department of Health and Human Services Division of Health Service Regulation Health Planning and Certificate of Need Section 2704 Mail Service Center Raleigh, NC 27699-2704

Re: Project ID # E-11630-18, Mobile PET/CT Scanner, Statewide Notice of Exempt Equipment Replacement

Dear Ms. Mitchell:

We are writing on behalf of Insight Health Corp. d/b/a Rayus Radiology ("Rayus") to notify the Agency of a planned equipment replacement that is exempt from CON review pursuant to N.C.G.S. § 131E-184(a)(7) and 10A NCAC 14C.0303. Rayus proposes to replace its existing mobile PET/CT Scanner currently in operation in N.C.

InSight Health Corp. (now d/b/a Rayus) was awarded a CON in 2021 to acquire a mobile PET/CT scanner, assigned Project ID #E-11630-18 with a statewide service area. The mobile PET/CT scanner has been in operation in North Carolina since June 2022. It is "currently in use" as defined by 10A NCAC 14C.0303(b) because ot has been used by Rayus at least ten times to provide PET/CT services within the past twelve months. The existing PET/CT scanner is a Siemens Horizon mobile PET/CT scanner, internally designated by Rayus as Unit S1390S.

Rayus will replace the existing unit with a United model 550i digital PET/CT scanner, which will be used for the same diagnostic purposes and will serve the same route and host sites in North Carolina. The replacement unit is designated by Rayus as U1409L ("Replacement Equipment"). The Replacement Equipment is comparable medical equipment with respect to the existing PET/CT scanner, and will be purchased for the sole purpose of replacing the existing PET/CT scanner, which will be sold or otherwise disposed of when replaced. Both are mobile PET/CT scanners. They are thus functionally similar, employ the same technology and are used for the same diagnostic purposes. The Replacement Equipment will not



Michaela Mitchell, Chief March 6, 2024 Page 2

be used to provide a new health service. A replacement equipment comparison form is attached as Exhibit A. The capital cost of the Replacement Equipment is below \$3,000,000 as shown on Exhibit A.

During the week that the Replacement Equipment is delivered and is being installed, Rayus plans to continue to scan patients on the PET/CT scanner. Simultaneously, applications training will need to be conducted for technologists on the Replacement Equipment, consisting of scanning a very limited volume of patients for approximately three to four days to build and adjust protocols. After that initial installation and training period, the existing PET/CT scanner, Unit S1390S, will be taken out of service and removed from the State.

We respectfully request that the Agency confirm receipt of this notice and confirm that the replacement of the existing equipment with Unit U1409L is exempt from CON review pursuant to N.C.G.S. § 131E-184(a)(7). Rayus anticipates the delivery of the Replacement Equipment approximately May, 2024. Thank you for your consideration, and we look forward to hearing from you soon.

Sincerely,

Marcus C. Hewitt

Enclosures

EQUIPMENT COMPARISON

	EXISTING	REPLACEMENT
	EQUIPMENT	EQUIPMENT
Type of Equipment (List Each Component)	Mobile PET/CT Scanner	Mobile PET/CT Scanner
Manufacturer of Equipment	Siemens	United
Model	Horizon	550i
Serial Number	94784	230068
Provider's Method of Identifying Equipment	S1390S	U1409L
Specify if Mobile or Fixed	Mobile	Mobile
Date of Acquisition of Each Component	NA	TBD
Does Provider Hold Title to Equipment or Have a Capital Lease?	Owned	To be owned
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <use attached="" form=""></use>	NA	\$1,850,970
Total Cost of Equipment	\$1,410,000	\$1,850,970
Fair Market Value of Equipment	NA	\$
Net Purchase Price of Equipment	NA	\$
Locations Where Operated	Route in NC	Route in NC
Number Days In Use/To be Used in N.C. Per Year		
Percent of Change in Patient Charges (by Procedure)	NA	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0%
Type of Procedures Currently Performed on Existing Equipment	PET/CT	NA
Type of Procedures New Equipment is Capable of Performing	NA	PET/CT

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project Name: Replacement of mobile PET/CT Unit S1390S with Unit U1409L

Provider/Company: <u>Insight Health Corp. d/b/a Rayus Radiology</u> A. <u>Site Costs</u>		
(1) Full purchase price of land	\$	
Acres Price per Acre \$	-	
(2) Closing costs	\$	
(3) Site Inspection and Survey	\$	
(4) Legal fees and subsoil investigation	\$	
(5) Site Preparation Costs	Φ	
Soil Borings		
Clearing-Earthwork \$		
Fine Grade For Slab \$		
Roads-Paving		
Concrete Sidewalks \$		
Water and Sewer \$		
Footing Excavation \$		
Footing Backfill \$		
Termite Treatment \$		
Other (Specify) \$		
Sub-Total Site Preparation Costs	\$	
(6) Other (Specify)	\$	
(7) Sub-Total Site Costs		\$
B. Construction Contract		
(8) Cost of Materials		
General Requirements \$		
Concrete/Masonry \$		
Woods/Doors & Windows/Finishes \$		
Thermal & Moisture Protection \$		
Equipment/Specialty Items \$ Mechanical/Electrical \$		
Other (Specify) \$	•	
Sub-Total Cost of Materials	\$	
(9) Cost of Labor	\$	
(10) Other (Specify)	\$	
(11) Sub-Total Construction Contract	S	
C. Miscellaneous Project Costs		
(12) Building Purchase	<u>\$</u>	
(13) Fixed Equipment Purchase/Lease	\$	
(14) Movable Equipment Purchase/Lease	\$ <u>1,850,970</u>	
(15) Furniture	\$	
(16) Landscaping	\$	
(17) Consultant Fees		
Architect and Engineering Fees \$		
Legal Fees\$		
Market Analysis \$		
Other (Specify)\$		
Other (Specify) \$		
Sub-Total Consultant Fees	\$	
(18) Financing Costs (e.g. Bond, Loan, etc.).	\$	
(19) Interest During Construction.	\$	
(20) Other (Specify)	\$	
(21) Sub-Total Miscellaneous	Ψ	\$1,850,970
(22) Total Capital Cost of Project (Sum A-C above)		\$1,850,970
I certify that, to the best of my knowledge, the costs of the proposed project named al	bove are complete and correct.	
	Date Certified:	
(Signature of Licensed Architect or Engineer)	Bate certified.	
assure that, to the best of my knowledge, the above costs for the proposed project as out the proposed project as described.	re complete and correct and that	at it is my intent to carry
1281, 10-1		
the Dayy Yr Interin Services	Date Signed: 3	6-24
Signature and Title of Officer Authorized to Represent Provider/Company)		

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

To: <u>Stancil, Tiffany C</u>

Subject: FW: [External] Exemption Notice (Replacement Equipment) - Mobile PET/CT PID #E-11630-18

Date: Thursday, March 7, 2024 1:49:40 PM

Attachments: Exemption Notice - Replacement Equipment (U1409L Replace S1390S)(156012779.1)-C.pdf

Hi Tiffany,

Would you mind logging this and assigning it to Cindy?

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

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From: Hewitt, Marcus C. <MHewitt@foxrothschild.com>

Sent: Wednesday, March 6, 2024 5:01 PM

To: Mitchell, Micheala L < Micheala. Mitchell@dhhs.nc.gov>; Pittman, Lisa

<lisa.pittman@dhhs.nc.gov>

Cc: Fradenburg, Susan M. <SFradenburg@foxrothschild.com>

Subject: [External] Exemption Notice (Replacement Equipment) - Mobile PET/CT PID #E-11630-18

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Ms. Mitchell and Ms. Pittman,

We are writing on behalf of Insight Health Corp.

Please see the attached letter regarding replacement of the mobile PET/CT scanner, Project ID #E-11630-18, which is exempt from CON review pursuant to NC Gen. Stat. Section 131E-184.

-Marc
Marcus C Hewitt
Partner
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