



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

May 12, 2020

Catharine W. Cummer  
[catharine.cummer@duke.edu](mailto:catharine.cummer@duke.edu)

**Exempt from Review – Replacement Equipment**

**Record #:** 3249  
**Facility Name:** Duke Regional Hospital  
**FID #:** 923142  
**Business Name:** Duke University Health System, Inc.  
**Business #:** 640  
**Project Description:** Replace x-ray equipment in Diagnostic Room 2 at the hospital  
**County:** Durham

Dear Ms. Cummer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of March 17, 2020, 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 Luminos Agile Max x-ray equipment to replace the GE Precision x-ray equipment. 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, Radiation Protection and Acute and Home Care Licensure and Certification 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,

Michael J. McKillip  
Project Analyst

Martha J. Frisone  
Chief

cc: Construction Section, DHSR  
Radiation Protection Section, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR

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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



**Catharine W. Cummer**  
Regulatory Counsel, Strategic Planning

March 17, 2020

Via Electronic Mail

Ms. Martha Frisone  
Mr. Michael McKillip  
Certificate of Need Section  
Division of Health Service Regulation  
2704 Mail Service Center  
Raleigh, NC 27699-2704

Re: Equipment Replacement Project at Duke Regional Hospital

Dear Ms. Frisone and Mr. McKillip:

On behalf of the Duke University Health System, I am writing to provide prior written notice of an equipment replacement project and to request the Section's written confirmation that the project is exempt from certificate of need review.

The project involves the replacement of x-ray equipment at Duke Regional Hospital in space identified as Diagnostic Room 2. This project is exempt from certificate of need review pursuant to N.C.G.S. 131E-184(a)(7) and 10A NCAC 14C .0303. This replacement equipment is comparable to the existing X-ray equipment, and the existing equipment will be removed from operation in North Carolina. An equipment comparison form and capital cost form is enclosed.

Alternatively, this equipment replacement project satisfies the requirements under N.C.G.S. 131E-184(f) for "replacement equipment that exceeds the two million dollar (\$2,000,000) threshold set forth in G.S. 131E-176(22) if all of the following conditions are met:

- (1) The equipment being replaced is located on the main campus.
- (2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
- (3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection."

Ms. Martha Frisone  
Mr. Michael McKillip  
March 17, 2020  
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The equipment to be replaced is on the main campus of the licensed hospital and did not require a CON for its original acquisition as a result of its cost below any major medical equipment threshold.

If you have questions or need any further information, please let me know. Thank you for your attention to this request.

Very truly yours,

*Catharine W. Cummer*

Catharine W. Cummer

Enclosures

EQUIPMENT COMPARISON  
DUKE REGIONAL HOSPITAL X-RAY

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Xray	Xray
Manufacturer of Equipment	GE	Siemens
Tesla Rating for MRIs	NA	NA
Model Number	Precision 500D	Luminos Agile Max
Serial Number	BRDTTZ	NA
Provider's Method of Identifying Equipment	Diagnostic Room 2	Diagnostic Room 2
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	NA	NA
Mobile Tractor Serial Number/VIN #	NA	NA
Date of Acquisition of Each Component	2005	2020
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	NA
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	310,391	967,000
Total Cost of Equipment	249,160	523,980
Fair Market Value of Equipment	0	523,980
Net Purchase Price of Equipment	249,160	523,980
Locations Where Operated	Duke Regional Hospital	Duke Regional Hospital
Number Days In Use/To be Used in N.C. Per Year	365	365
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	XRay procedures	Xray procedures
Type of Procedures New Equipment is Capable of Performing	NA	NA

**PROPOSED TOTAL CAPITAL COST OF PROJECT**

**Project Name:**

**Provider/Company:**

**A. Site Costs**

(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			
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) <b>Sub-Total Site Costs</b>			\$ _____

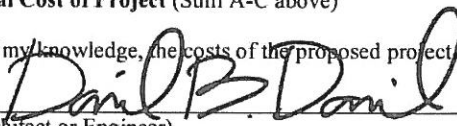
**B. Construction Contract**

(8) Cost of Materials			
General Requirements	\$ _____		
Concrete/Masonry	\$ _____		
Woods/Doors & Windows/Finishes	\$ _____		
Thermal & Moisture Protection	\$ _____		
Equipment/Specialty Items	\$ _____		
Mechanical/Electrical	\$ _____		
Other (Specify)	\$ 280,000		
Sub-Total Cost of Materials.....		\$ _____	
(9) Cost of Labor.....		\$ _____	
(10) Other (Contingency).....			\$ _____
(11) <b>Sub-Total Construction Contract</b>			\$ 368,290

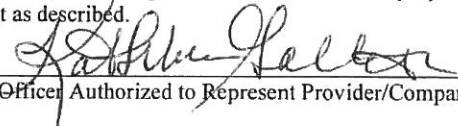
**C. Miscellaneous Project Costs**

(12) Building Purchase.....		\$ _____	
(13) Fixed Equipment Purchase/Lease		\$ 540,000	
(14) Movable Equipment Purchase/Lease		\$ _____	
(15) Furniture		\$ _____	
(16) Landscaping		\$ _____	
(17) Consultant Fees			
Architect and Engineering Fees	\$ 55,000		
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 (CON/Permit/DHSR)			\$ 3,710
(21) <b>Sub-Total Miscellaneous..</b>			\$ 598,710
(22) <b>Total Capital Cost of Project (Sum A-C above)</b>			\$ 967,000

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


Date Certified: 03/16/2020  
 \_\_\_\_\_  
 (Signature of Licensed Architect or Engineer)

I assure that, to the best of my knowledge, the above costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.


Date Signed: 3/17/2020  
 \_\_\_\_\_  
 (Signature and Title of Officer Authorized to Represent Provider/Company)