



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

November 24, 2021

Catharine Cummer, Regulatory Counsel, Strategic Planning
catharine.cummer@duke.edu

Exempt from Review – Replacement Equipment

Record #: 3748
Date of Request: November 12, 2021
Facility Name: Duke Raleigh Hospital
FID #: 923421
Business Name: Duke University Health System, Inc.
Business #: 640
Project Description: Replace a cardiac catheterization system
County: Wake

Dear Ms. Cummer:

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(f). Therefore, you may proceed to acquire without a certificate of need the Philips Azurion cardiac catheterization equipment to replace the Philips Alura FD20 cardiac catheterization equipment (Serial # 4867). This determination is based on your representations that the existing unit will be re-purposed as interventional radiology equipment and will not be used as cardiac catheterization equipment 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,

[Handwritten signature of Michael J. McKillip]

Michael J. McKillip
Project Analyst

[Handwritten signature of Micheala Mitchell]

Micheala Mitchell
Chief

cc: Radiation Protection Section, DHSR
Construction 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



Catharine W. Cummer
Regulatory Counsel, Strategic Planning

November 12, 2021

Via Electronic Mail

Ms. Micheala Mitchell, Chief
Ms. Lisa Pittman, Assistant Chief
Mr. Michael McKillip, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Equipment Replacement Project at Duke Raleigh Hospital

Dear Ms. Mitchell, Ms. Pittman, 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 cardiac catheterization equipment originally installed pursuant to a CON (and subsequently replaced) at Duke Raleigh Hospital.

Duke Raleigh Hospital has recently decreased the number of cardiac catheterization labs operated pursuant to a services agreement with DLP Cardiac Partners from two to one. With the resulting decrease in overall cardiac cath capacity, the Duke Raleigh Hospital-owned cath lab equipment, which is seven years old, needs to be replaced, in order to minimize any downtime for maintenance and service as the equipment ages.

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.”

Main campus

The existing and replacement catheterization equipment are/will be located in the main Duke Raleigh Hospital building. This is on the “main campus” of the facility, as defined in 131E-176(14n), as “[t]he site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building” and “[o]ther areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.”

Duke Raleigh Hospital is a licensed health service facility (license available upon request), and the main hospital building from which Duke Raleigh Hospital provides its inpatient clinical services and exercises financial and administrative control over all Duke Raleigh Hospital services is located at 3400 Wake Forest Road in Raleigh.

Floor plans showing the location of the project within the hospital building are enclosed.

Certificate of Need

Duke Raleigh Hospital originally acquired a single unit of cardiac catheterization equipment pursuant to project J-6753-03. After this replacement, the inventory of Duke-owned cardiac cath labs at the hospital will remain at one.

Replacement Equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definition. A completed Equipment Comparison form is enclosed. Both the existing equipment and the replacement equipment are equipment capable of providing cardiac catheterization and interventional radiology procedures.

A copy of the equipment quotation is available upon request. Duke will not acquire any other major medical equipment or develop any other new institutional health services other than those described in Section 131E-176(16)(b).

Disposition of Existing Equipment

After the installation of the replacement cardiac catheterization lab, Duke Raleigh Hospital will discontinue cardiac catheterization procedures on the existing equipment. However, rather than simply disposing of the equipment out of state, Duke Raleigh Hospital seeks confirmation that it may continue to use this equipment for non-cardiac cath services, namely, interventional radiology procedures that do not meet the definition of cardiac catheterization. Accordingly, the total inventory of cardiac cath equipment at the hospital will not change.

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Duke Raleigh Hospital could trade in the existing equipment, and then repurchase it from the vendor as non-cardiac catheterization equipment for under the \$2 million cost threshold applicable for major medical equipment; interventional radiology equipment under that cost threshold does not constitute a new institutional health service for which a CON is required. The total cost of the existing equipment was only \$1.2M at its original acquisition, and its current depreciated/book value is zero. The proposed arrangement – redeployment of the existing equipment for any remainder of its useful life as solely interventional radiology equipment – achieves the same result.

If you have questions or need any further information, please let me know. We would appreciate your confirmation that this project is exempt from CON review. Thank you for your attention to this request.

Very truly yours,

Catharine W. Cummer

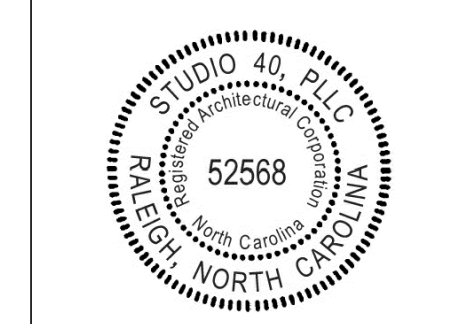
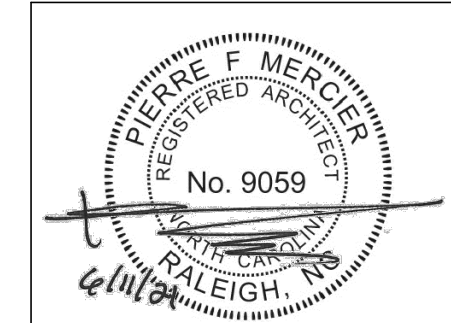
Catharine W. Cummer

Enclosures

**EQUIPMENT COMPARISON
DUKE RALEIGH HOSPITAL CARDIAC CATHETERIZATION EQUIPMENT REPLACEMENT**

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment	Cardiac Cath/Angio	Cardiac Cath/Angio
Manufacturer of Equipment	Philips	Philips
Tesla Rating for MRIs	N/A	N/A
Model Number	Allura FD20	Azurion 7 C20
Serial Number	4867	TBD
Provider's Method of Identifying Equipment	Cath/IR Lab	Lab 1
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date Acquired	August 2014	TBD
Does Provider Hold Title to Equipment or Have a Capital Lease?	Own	Capital purchase
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	\$1.7M	\$5.1M
Total Cost of Equipment	\$1.2M	\$1.2M
Fair Market Value of Equipment	NA	\$1.2M
Net Purchase Price of Equipment	NA	\$1.2M
Locations Where Operated	Duke Raleigh Hospital	Duke Raleigh Hospital
Number of Times Existing Equipment was Used to Provide a Health Service during the 12 months prior to the Date of the Written Notice	>10 for cath and interventional radiology procedures (equipment used daily during normal business hours and available for use 24/7)	N/A
Type of Procedures Currently Performed on Existing Equipment	Cath/Interventional Radiology	NA
Type of Procedures New Equipment is Capable of Performing	NA	Cath/Interventional Radiology/EP

Date of last revision: 12/4/2020



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FPDC PROJECT # 3970HSRH
PREPARED FOR
DUKE HEALTH /
FACILITY PLANNING,
DESIGN & CONSTRUCTION

PROPOSED INTERIOR ALTERATIONS FOR:
**Duke Raleigh Hospital
Cath Lab Equipment Upgrades**
3400 WAKE FOREST ROAD
RALEIGH, NC 27609
FPDC PROJECT #3970HSRH
DHSR #HL-12289

SHEET NAME:
**OVERALL HOSPITAL
FIRST FLOOR/
LIFE SAFETY PLAN**

REVISIONS:
DATE: 06.11.21
PROJECT NO.: 20-027
DRAWN BY: PFM

SHEET NO.:
A0.1

PERMIT SET



1 OVERALL FIRST FLOOR / LIFE SAFETY PLAN
NTS