

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

May 13, 2022

Catharine Cummer Catharine.cummer@duke.edu

Exempt from Review – Replacement Equipment		
Record #:	3892	
Date of Request:	May 11, 2022	
Facility Name:	Duke University Hospital	
FID #:	943138	
Business Name:	Duke University Health System, Inc.	
Business #:	640	
Project Description:	Replace existing CT scanner	
County:	Durham	

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 Siemens Somatom Force CT scanner to replace the GE Lightspeed VCT 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,

Vin Mymandi

Kim Meymandi Project Analyst

Micheala Nitchell

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

May 11, 2022

Via Electronic Mail

Ms. Micheala Mitchell Ms. Kimberly Meymandi Division of Health Service Regulation 2704 Mail Service Center Raleigh, NC 27699-2704

Re: Exempt Replacement Project at Duke University Hospital

Dear Ms. Mitchell and Ms. Meymandi:

The purpose of this letter is to request the CON Section's written confirmation that the acquisition of replacement CT scanner equipment 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.

As set forth below, we believe that Duke University Hospital's project meets these requirements and is exempt from certificate of need review.

(1) Main Campus

The purpose of this project is to replace an existing CT scanner located in the Duke University Hospital emergency department, which is part of the main building of Duke University Hospital. The "main campus" of the facility is defined in N.C.G.S. 131E-176(14n) to include

Ms. Micheala Mitchell Ms. Kimberly Meymandi May 11, 2022 Page 2

both "[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."

In this case, Duke University Hospital is a licensed health service facility, and the main hospital building from which Duke University Hospital provides its clinical services and exercises financial and administrative control is the physically contiguous structure that includes Duke South, Duke North, the Duke Children's Hospital, the Duke Medicine Pavilion, Duke Central Tower, the Morris Clinic, the Duke Cancer Center, the Wadsworth Building, and the Hudson Building. The hospital's current license and floorplans showing the location of this replacement project are included.

(2) Previous Certificate of Need Exemption

The existing equipment was acquired and put into service in 2008 pursuant to the exemption notice included with this request. Please note that the equipment was subsequently relocated within the hospital to the emergency department.

(3) Replacement equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definitions. A completed Equipment Comparison form is enclosed. Both the existing equipment and the replacement equipment provide cardiac catheterization procedures. The total project cost exceeds \$2,000,000 reflecting major medical equipment, related equipment, and renovation/installation expenses. Copies of the equipment quotations are 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). The existing equipment will be traded into the vendor and will accordingly be taken out service in North Carolina.

Thank you for your attention to this request. If you have questions about this information, please let me know.

Very truly yours,

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Catharine W. Cummer

Enclosures

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Division of Health Service Regulation

Effective January 01, 2022, this license is issued to Duke University Health System, Inc.

to operate a hospital known as **Duke University Hospital** located in Durham, North Carolina, Durham County.

This license is issued subject to the statutes of the State of North Carolina, is not transferable and shall remain in effect until amended by the issuing agency.

> Facility ID: 943138 License Number: H0015

Bed Capacity: 1048 General Acute 1048

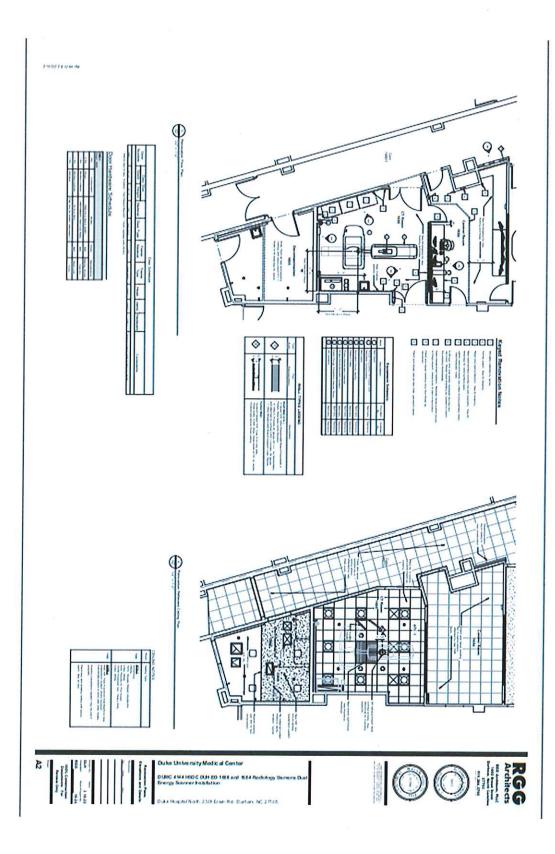
Dedicated Inpatient Surgical Operating Rooms: 6 Dedicated Ambulatory Surgical Operating Rooms: 9 Shared Surgical Operating Rooms: 50 Dedicated Endoscopy Rooms: 11

Authorized by:

Secretary, N.C. Department of Health and Human Services



Director, Division of Health Service Regulation





North Carolina Department of Health and Human Services **Division of Health Service Regulation Certificate of Need Section**

2704 Mail Service Center Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor Carmen Hooker Odom, Secretary

http://facility-services.state.nc.us

Lee Hoffman, Section Chief Phone: 919-855-3873 Fax: 919-733-8139

August 13, 2007

Duncan Yaggy, Chief Planning Officer Duke University Health System 3100 Tower Boulevard Suite 600, Box 80 Durham, NC 27707

Exempt from Review - Replacement Equipment/Duke University Hospital/Replace a GE 4-slice RE: computed tomography (CT) scanner with a new GE 64-slice CT scanner/Durham County FID # 943138

Dear Mr. Yaggy:

In response to your letter of July 11, 2007, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the GE Lightspeed VCT CT scanner to replace the existing GE QX/I Lightspeed CT scanner [Serial # 346618CN2]. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory.

It should be noted that this 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 Agency 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

Certificate of Need Section

cc: Medical Facilities Planning Section, DFS Construction Section, DFS



Location: 701 Barbour Drive Dorothea Dix Hospital Campus Raleigh, N.C. 27603 An Equal Opportunity / Affirmative Action Employer

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	FOLIIPMENT	REPLACEMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	CT Scanner	CT Scanner
Manufacturer	GE	Siemens
Model number	Lightspeed VCT	Somatom Force
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	DUH ED CT2	DUH ED CT2
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2008	2023
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project <attach a="" capital="" cost="" form="" projected="" signed=""></attach>	N/A	\$3.2M
Total cost of the equipment		\$1.75M
Location of the equipment <attach a="" equipment="" for="" if="" mobile="" necessary="" separate="" sheet=""></attach>	DUH ED CT2	DUH ED CT2
Document that the existing equipment is currently in use	Yes	
Will the replacement equipment result in any increase in the average charge per procedure?		No
If so, provide the increase as a percent of the current average charge per procedure		
Will the replacement equipment result in any increase in the average operating expense per procedure?		No
If so, provide the increase as a percent of the current average operating expense per procedure		
Type of procedures performed on the existing equipment <attach a="" if="" necessary="" separate="" sheet=""></attach>	CT scans of head, neck, spine, chest, abdomen, pelvis, upper, lower extremities both diagnostic and	

Date of
f last r
evision:

Type of procedures the replacement equipment will perform <attach a="" if="" necessary="" separate="" sheet=""></attach>	
	angiography for emergency department patients presenting as trauma, stroke, via ambulance, or ambulatory into the ED.
CT scans of head, neck, spine, chest, abdomen, pelvis, upper, lower extremities both diagnostic and angiography for emergency department patients presenting as trauma, stroke, via ambulance, or ambulatory into the ED.	