



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

March 29, 2021

Catharine Cummer
Catharine.cummer@duke.edu

Exempt from Review – Replacement Equipment

Record #: 3509
Date of Request: March 24, 2021
Facility Name: Duke University Hospital
FID #: 943138
Business Name: Duke University Health System, Inc.
Business #: 3311
Project Description: Replace existing heart-lung bypass equipment
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(a)(7). Therefore, you may proceed to acquire without a certificate of need the Spectrum Medical Quantum Heart-Lung Machine to replace the Sorin S5 Heart-Lung Machine. 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,

Handwritten signature of Kim Meymandi in blue ink.

Kim Meymandi
Project Analyst

Handwritten signature of Lisa Pittman in blue ink.

Lisa Pittman
Acting Chief, Certificate of Need

cc: 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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



Catharine W. Cummer
Regulatory Counsel, Strategic Planning

March 24, 2021

Via Electronic Mail

Ms. Lisa Pittman
Ms. Kimberly Meymandi
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Exempt Bypass Equipment Replacement Project at Duke University Hospital

Dear Ms. Pittman and Ms. Meymandi:

The purpose of this letter is to request the CON Section's written confirmation that the acquisition of replacement heart-lung bypass equipment at Duke University Hospital is exempt from certificate of need review under NCGS 131E-184(a)(7). The equipment is nearing end of life. A completed equipment comparison form is enclosed, and the vendor's quote for the new equipment is available for your review upon request. The existing equipment is currently in use at Duke University Hospital, but upon acquisition of the replacement equipment the existing equipment will be removed from service in the state. Please let me know if you have any questions about this project.

Very truly yours,

Catharine W. Cummer

Catharine W. Cummer

Enclosure

EQUIPMENT COMPARISON – DUH BYPASS EQUIPMENT

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Sorin S5 Heart-Lung Machine	Spectrum Medical Quantum Heart-Lung Machine
Manufacturer of Equipment	LivaNova- Sorin	Spectrum Medical
Tesla Rating for MRIs		
Model Number	Stockert S5 48-31-10	
Serial Number	CE 97965 Asset Tag 7744	
Provider's Method of Identifying Equipment		
Specify if Mobile or Fixed	Semi-mobile within OR suites	Semi-mobile within OR suites
Mobile Trailer Serial Number/VIN #		
Mobile Tractor Serial Number/VIN #		
Date of Acquisition of Each Component	2010	
Does Provider Hold Title to Equipment or Have a Capital Lease?	Duke Owned	
Specify if Equipment Was/Is New or Used When Acquired	Was New	
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	\$168,863	\$406,830
Total Cost of Equipment	\$168,863	\$393,830
Fair Market Value of Equipment		
Net Purchase Price of Equipment		
Locations Where Operated	Duke North and Duke Medical Pavilion Operating Rooms	Duke North and Duke Medical Pavilion Operating Rooms
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	Heart-lung bypass	NA
Type of Procedures New Equipment is Capable of Performing	NA	Heart-lung bypass

From: [Catharine Cummer](#)
To: [Waller, Martha K](#)
Subject: [External] To State Exemption Notice DUH bypass replacement
Date: Wednesday, March 24, 2021 10:51:51 AM
Attachments: [To State Exemption Notice DUH bypass replacement.pdf](#)
[Equipment comparison form -- DUH bypass 2021.doc](#)

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Martha,
I hope you're doing well. Could you please share the attached with Lisa and Kim for review? Thank you!

Catharine

Catharine Cummer
Regulatory Counsel, Strategic Planning, Duke University Health System
3100 Tower Blvd, Suite 1300, Durham NC 27707
catharine.cummer@duke.edu | DukeHealth.org | (919) 668-0857 (office) | (919) 423-6928 (cell)



In support of Duke Health's values,
I stand for Black lives and against systemic racism.