



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER  
GOVERNOR

MANDY COHEN, MD, MPH  
SECRETARY

MARK PAYNE  
DIRECTOR

June 30, 2017

Catharine W. Cumber  
3100 Tower Boulevard, Suite 1300  
Durham, NC 27707

**Exempt from Review – Replacement Equipment**

**Record #:** 2312  
**Facility Name:** Duke Regional Hospital  
**FID #:** 923142  
**Business Name:** Duke University Health System, Inc.  
**Business #:** 640  
**Project Description:** Replace bypass equipment  
**County:** Durham

Dear Ms. Cumber:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 23, 2017, 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 S5 Heart Lung Perfusion System to replace the S3 Heart Lung System. 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 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,

Bernetta Thorne-Williams  
Project Analyst

Martha J. Frisone  
Chief, Healthcare Planning and  
Certificate of Need Section

cc: Construction Section, DHSR  
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR

**HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION**  
WWW.NCDHHS.GOV

TELEPHONE 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603

MAILING ADDRESS: 2704 MAIL SERVICE CENTER • RALEIGH, NC 27699-2704

AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER



Record# 2812  
FID#923142

# Duke University Health System

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

June 23, 2017

Via Electronic Mail

Ms. Martha Frisone  
Chief, 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 Regional Hospital – Bypass Equipment

Dear Ms. Frisone:

I am writing to provide you with prior written notice of the planned acquisition of replacement bypass equipment at Duke Regional Hospital. A completed equipment comparison form and capital cost form are enclosed. The total project cost is less than \$2 million. The vendor's quote is available for your review upon request. The existing equipment is currently in use at Duke Regional Hospital, but upon acquisition of the replacement equipment the existing equipment will be removed from service in the state unless its use elsewhere is first approved by the state.

It is our understanding that with this prior notice, this acquisition is exempt from certificate of need review as the acquisition of replacement equipment pursuant to N.C.G.S. Section 131E-184, and we accordingly intend to proceed immediately with this project. If you have any questions, please let me know as soon as possible.

Thank you for your attention to this matter. Should you have any questions, please let me know.

Very truly yours,

Catharine W. Cummer

Enclosures

EQUIPMENT COMPARISON

EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
S3 Heart Lung System	S5 Heart Lung Perfusion System
Stockert	LivaNova/SorinGroup
N/A	N/A
S3 console 43-40-000	tbd
43S3098	tbd
Clinical Engineering #	Clinical Engineering #
Mobile	Mobile
N/A Cart	N/A
N/A Cart	N/A
12/1/1992	tbd
Yes, hold title	Will hold title to new equipment
New	Will purchase new
N/A	\$200,623.00
\$94,365.00	\$200,623.00
0 (equipment not supported, end of life)	\$200,623.00
\$94,365.00	\$199,553.00
Duke Regional Hospital	Duke Regional Hospital
365	365
NA	0
NA	0
Back up to the current machine for cardiopulmonary bypass	NA
NA	Cardiopulmonary Bypass

**PROPOSED TOTAL CAPITAL COST OF PROJECT**

**Project Name: SS Heart Lung Perfusion System**  
**Provider/Company: Liva Nova/Sorin Group**

**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) 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			\$ _____

**C. Miscellaneous Project Costs**

(12) Building Purchase.....		\$ _____	
(13) Fixed Equipment Purchase/Lease		\$ _____	
(14) Movable Equipment Purchase/Lease		\$ 200,623.00	
(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..			\$ _____
(22) Total Capital Cost of Project (Sum A-C above)			\$ 200,623.00

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

Date Certified: \_\_\_\_\_

(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: 6/22/17

(Signature and Title of Officer Authorized to Represent Provider/Company)