



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

JOSH STEIN • Governor

DEVPUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

April 11, 2025

Ms. Denise M. Gunter

Denise.gunter@nelsonmullins.com

Exempt from Review – Replacement Equipment

Record #: 4750

Date of Request: April 7, 2025

Facility Name: FirstHealth Moore Regional Hospital

FID #: 943358

Business Name: FirstHealth of the Carolinas, Inc.

Business #: 2724

Project Description: Replace cardiac catheterization equipment

County: Moore

Dear Ms. Gunter:

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 Canon V9.5 Alphenix Sky Ceiling Vascular System C-arm to replace the Toshiba Inferix VP-I C-arm. 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,

Tanya M. Saporito
Project Analyst

Micheala Mitchell
Chief

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

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

April 7, 2025

Via E-mail

Micheala Mitchell, Chief
Healthcare Planning and Certificate of Need Section
North Carolina Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Replacement Equipment Exemption for FirstHealth of the Carolinas, Inc. (Health Service Area V, Moore County)

Dear Ms. Mitchell:

On behalf of FirstHealth of the Carolinas, Inc. ("FirstHealth") and pursuant to N.C. Gen. Stat. § 131E-184(a)(7), I am writing to inform the Agency of FirstHealth's plan to replace an existing C-arm in Cath Lab #2 at FirstHealth Moore Regional Hospital in Pinehurst, North Carolina. The replacement equipment comparison form is attached as **Exhibit A**, and the capital cost form is attached as **Exhibit B**.

A C-arm provides real-time x-ray imaging to guide catheters and other instruments through the blood vessels to the heart, enabling cardiologists to visualize structures and perform procedures like angiograms and angioplasties. The existing C-arm in Cath Lab #2 is a Toshiba Infinix VP-1 that was purchased in 2008 (the "Existing Equipment"). The Existing Equipment is nearing the end of its useful life, and FirstHealth has decided to replace it with a Canon V9.5 Alphenix Sky Ceiling Vascular Equipment (the "Replacement Equipment"). The total capital costs are \$ 1,355,796, which includes all costs essential to acquiring and making the equipment operational. A video showing the equipment is at <https://us.medical.canon/products/angiography/interventional-cardiology/#/resources/videos/angiography/alphenix-sky/>.

The sole purpose of the project is to replace the Existing Equipment. When the Replacement Equipment is ready to be used, FirstHealth will dispose of the Existing Equipment. The Existing Equipment will not be used in North Carolina again without CON approval. The Existing Equipment meets the requirements of 10A NCAC 14C.0303(b) because it has been used at least 10 times to provide a health service during the 12

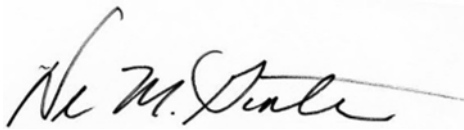
Micheala Mitchell
April 7, 2025
Page 2

months prior to the date of this letter. None of the exclusions in 10A NCAC 14C.0303(c) applies here.

Since the project meets the requirements of N.C. Gen. Stat. § 131E-176(22a) and 10A NCAC 14C. 0303(a)-(c), we respectfully request that the Agency issue an exemption pursuant to N.C. Gen. Stat. § 131E-184(a)(7). Please let me know if you need any additional information.

Thank you for your time and consideration. With best personal regards.

Sincerely,

A handwritten signature in black ink, appearing to read "Denise M. Gunter", with a long horizontal flourish extending to the right.

Denise M. Gunter

Attachments

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type : Cardiac Cath lab 2 (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)		
Manufacturer	Toshiba	Canon
Model number	Infenix VP-I	V9.5 Alphenix Sky Ceiling Vascular System
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	Cath lab #2	Cath lab #2
Is the equipment mobile or fixed?	fixed	fixed
Date of acquisition	11-15-2008	4/1/25
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 signed Projected Capital Cost form>		\$1,355,796
Total cost of the equipment	\$1,274,748	\$869,760
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	Cath Lab #2	Cath Lab #2
Document that the existing equipment is currently in use	See letter	
Will the replacement equipment result in any increase in the average charge per procedure ?	NA	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 ?	NA	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 separate sheet if necessary>	Cardiac cath	Cardiac Cath
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	EP, Cath, structural heart

Date of last revision: 5/17/19

Projected Capital Cost Form – MRH Cath Lab 2

Building Purchase Price	\$0
Purchase Price of Land	\$0
Closing Costs	\$0
Site Preparation	\$0
Construction/Renovation Contract(s)	\$338,640.
Landscaping	\$0
Architect / Engineering Fees –	Incl. in Construction above \$0
Medical Equipment	\$869,760
Non-Medical Equipment	\$81,808
Furniture	\$0
Consultant Fees (specify)	\$0
Financing Costs	\$0
Interest during Construction	\$0
Other – Permit Fee & Contingency	\$65,588
Total Capital Cost	\$1,355,796

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

I certify that, to the best of my knowledge, the projected capital cost for the proposed project is complete and correct.

Signature of Licensed Architect or Engineer

Date Signed:

CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT

I certify that, to the best of my knowledge, the projected total capital cost for the proposed project is complete and correct and that it is our intent to carry out the proposed project as described.

Signature of Officer/Agent

Date Signed:

4/8/25

Signature of Officer/Agent

Administrative Director, PDC

Title of Officer/Agent

From: [Denise Gunter](#)
To: [Stancil, Tiffany C](#); [Waller, Martha K](#); [Tanya, Saporito](#)
Subject: [External] Replacement Equipment Exemption Letter for FirstHealth of the Carolinas, Inc. (HSA V)
Date: Monday, April 7, 2025 4:30:19 PM
Attachments: [Cath Lab #2 Exemption Letter.pdf](#)
[Exhibit A.pdf](#)
[Exhibit B.pdf](#)

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Good afternoon,

Attached for processing is a replacement equipment exemption request for FirstHealth.
Could you please let me know that you have received it?

Thanks.



DENISE M. GUNTER **PARTNER**
denise.gunter@nelsonmullins.com

She/Her/Hers

THE KNOLLWOOD | SUITE 530

380 KNOLLWOOD STREET | WINSTON-SALEM, NC 27103

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