

JOSH STEIN • Governor

DEVDUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

March 28, 2025

Robert A. Leandro robbleandro@parkerpoe.com

Exempt from Review – Replacement Equipment

Record #: 4733

Date of Request: March 17, 2025

Facility Name: UNC Health Blue Ridge

FID #: 943191

Business Name: DLP Cardiac Partners, LLC

Business #: 2314

Project Description: Replace an existing fixed cardiac catheterization lab

County: Burke

Dear Mr. Leandro:

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 GE Allia IGS 530 cardiac catheterization lab to replace the GE Innova 2100, model number 576724BU9, cardiac catheterization lab. 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,

Ena Lightbourne Project Analyst

Micheala Mitchell

Chief

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

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



Robert A. Leandro

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Charleston, SC
Charlotte, NC
Columbia, SC
Greenville, SC
Raleigh, NC
Spartanburg, SC
Washington, DC

March 17, 2025

VIA EMAIL

Micheala Mitchell Chief Health Planning and Certificate of Need Section Micheala.mitchell@dhhs.nc.gov

Re: Written Notice for Exemption from CON Review for Replacement of Cardiac Cath Lab

Dear Ms. Mitchell:

I am writing on behalf of my client DLP Cardiac Partners ("Cardiac Partners") to provide prior written notice pursuant N.C.G.S. § 131E-184(a)(7) for the replacement of a cardiac catheterization lab ("Cath Lab"). Cardiac Partners has operated a fixed GE Innova 2100IQ Cath Lab at UNC Health Blue Ridge Hospital in Morganton, North Carolina pursuant to Cardiac Partners Settlement Agreement with the Agency. That fixed Cath Lab became inoperable after a series of malfunctions and a temporary replacement Cath Lab has been used while Cardiac Partners determined if the existing Cath Lab could be repaired. *See* Exhibit A. January 24, 2025 Letter. Cardiac Partners has now determined that the existing Cath Lab will need to be permanently replaced.

The replacement Cath Lab that is being acquired by Cardiac Partners is comparable to the existing Cath Lab currently located at UNC Health Blue Ridge Hospital. It will be used for the same purposes as the existing fixed Cath Lab. *See* Comparison Chart, attached as Exhibit B. The existing fixed Cath Lab at issue was last used on January 17, 2025. Once the new fixed Cath Lab is installed, the temporary mobile Cath Lab and the legacy fixed Cath Lab will be removed from the state and will not be used unless a CON or CON exemption is obtained.

Based on the information provided, we request on behalf of Cardiac Partners that the Agency provide a written response confirming that our client may acquire a replacement Cath Lab without CON review. Should the Agency need additional information, please let

March 17, 2025 Page 2

me know as soon as possible. Thank you in advance for your attention to this matter and we look forward to hearing from you.

Sincerely,

Robb A. Leandro

Robus a. Labo

Exhibit A



JOSH STEIN · Governor **DEVDUTTA SANGVAI** • Secretary MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

January 27, 2025

Robert A. Leandro robbleandro@parkerpoe.com

Exempt from Review – Replacement Equipment

Record #:

4700

Date of Request:

January 24, 2025

Facility Name:

UNC Health Blue Ridge

FID#:

943191

Business Name:

DLP Cardiac Partners, LLC

Business #:

2314

Project Description:

Temporarily replace fixed cardiac catheterization lab with mobile cardiac

catheterization unit

County:

Burke

Dear Mr. Leandro:

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 utilize without a certificate of need the Phillips FD-20 mobile cardiac catheterization lab to temporarily replace the GE Innova 2100IQ fixed cardiac catheterization lab. This determination is based on your representations that the GE Innova 2100IO fixed cardiac catheterization lab will undergo repairs after which, upon completion of the repairs, the GE Innova 2100IQ fixed cardiac catheterization lab will return to service and the Phillips FD-20 mobile cardiac catheterization lab will be removed from the State 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,

Ena Lightbourne Project Analyst

Micheala Mitchell

Micheala Mitchell

Chief

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



Robert A. Leandro
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Atlanta, GA Charleston, SC Charlotte, NC Columbia, SC Greenville, SC Raleigh, NC Spartanburg, SC Washington, DC

January 24, 2025

VIA EMAIL

Micheala Mitchell, Chief Health Planning and Certificate of Need Section Micheala.mitchell@dhhs.nc.gov

Re: Written Notice for Exemption from CON Review for the Temporary Replacement of Mobile Cardiac Cath Lab

Dear Ms. Mitchell:

I am writing on behalf of my client DLP Cardiac Partners ("Cardiac Partners") to provide prior written notice pursuant N.C.G.S. § 131E-184(a)(7) for the temporary use of a mobile cardiac catheterization lab ("Cath Lab"). Currently Cardiac Partners operates a fixed GE Innova 2100IQ Cath Lab at UNC Health Blue Ridge Hospital in Morganton, North Carolina pursuant to Cardiac Partners Settlement Agreement with the Agency. That fixed Cath Lab is currently inoperable after a series of malfunctions and may need to be replaced. Cardiac Partners intends to temporarily use a Phillips FD-20 mobile cardiac Cath Lab that it owns but is not active in North Carolina as a temporary replacement while it determines if the fixed Cath Lab can be repaired or needs to be replaced. Once the fixed Cath Lab has been repaired or it is determined that a replacement Cath Lab is necessary, the mobile Cath Lab will be taken off site and will not be used again at UNC Health Blue Ridge Hospital. Should Cardiac Partners determine that the fixed Cath Lab needs to be permanently replaced it will provide separate notice to the Agency.

The temporary mobile Cath Lab that will be used is comparable to the existing fixed Cath Lab currently in use at UNC Health Blue Ridge Hospital. It will be used for the same purposes as the existing fixed Cath Lab. The fixed Cath Lab at issue was last used on January 17, 2025.

Based on the information provided, we request on behalf DLP Cardiac Partners that the Agency provide a written response confirming that our client may operate the temporary mobile

January 24, 2025 Page 2

Cath Lab without CON review. Should the Agency need additional information, please let me know as soon as possible. Thank you in advance for your attention to this matter and we look forward to hearing from you.

Sincerely,
Robus a. Luho

Robertt A. Leandro

RAL

From:

Mitchell, Micheala L

To:

Stancil, Tiffany C; Lightbourne, Ena

Cc:

Mckillip, Mike

Subject:

FW: [External] Cardiac Partners Letter Temporary Replacement Equipment Notice

Date:

Friday, January 24, 2025 4:36:02 PM

Attachments:

Cardiac Partners January 24 2025 Letter to Micheala Mitchell.pdf

Hi Tiffany- Can you log and assign this to Ena?

Ena-The provider's attorney has asked for a quick turnaround as it is for replacement cath equipment. Do you think you would be able to get to it by COB on Tuesday or Wednesday?

Mike- Gloria will be out the first 3 days of next week to participate in a hearing. If Ena can get it completed before Gloria returns, would you mind reviewing it?

Thanks,

Micheala

Micheala Mitchell, JD
NC Department of Health and Human Services
Division of Health Service Regulation
Section Chief, Healthcare Planning and CON Section
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704
Office: 919 855 3879

Micheala.Mitchell@dhhs.nc.gov

From: Leandro, Robert A. <robbleandro@parkerpoe.com>

Sent: Friday, January 24, 2025 4:28 PM

To: Mitchell, Micheala L < Micheala. Mitchell@dhhs.nc.gov>

Subject: [External] Cardiac Partners Letter Temporary Replacement Equipment Notice

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Ms. Mitchell,

Please find attached my client DLP Cardiac Partners' request to temporarily replace the cath lab it uses at UNC Health Blue Ridge Hospital. My understanding is that they need to have the temporary replacement up and running as soon as possible so I am hoping you will be able to expedite the Agency's response.

Have a great weekend.

Robb

Robert Leandro

Partner

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Exhibit B

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	cardiac cath lab	cardiac cath lab
Manufacturer of Equipment	GE	GE
Model Number	Innova 2100	Allia IGS 530
Serial Number	576724BU9	TBD
Provider's Method of Identifying Equipment	N/A	N/A
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 of Acquisition of Each Component	9/1/2009	April/May 2025
Does Provider Hold Tittle to Equipment or Have a Capital Lease?	Yes	It will when acquired
Specify if Equipment Was/Is New or Used When Acquired	New	Will Be New
Total Capital Cost of Project (Including Construction, etc.) *Use attached form*	976,402.16	907,692.87
Total Cost of Equipment	976,402.16	907,692.87
Fair Market Value of Equipment	5,000	907,692.87
Net Purchase Price of Equipment	976,402.16	907,692.87
Location Where Operated	UNC Blue Ridge	UNC Blue Ridge
Number days in Use/To be Used in N.C. Per Year	250	250
Percent Change in patient Charges (by Procedure)	0%	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	0%	0%
Type of Procedures Currently Performed on Existing equipment	cardiac catheterizations	N/A
Type of Pricedures New Equipment is Capable of Performing	N/A	cardiac catheterizations

From: Mitchell, Micheala L

To: Stancil, Tiffany C

 Subject:
 FW: [External] Cath Lab Replacement Notice

 Date:
 Tuesday, March 18, 2025 9:54:19 AM

 Attachments:
 DLP Cardiac Partners Replacment Notice.pdf

Morning Tiffany,

Would you mind logging and assigning to Ena?

Thanks!

Micheala Mitchell, JD

NC Department of Health and Human Services

Division of Health Service Regulation

Section Chief, Healthcare Planning and CON Section
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center

Raleigh, NC 27699-2704

Office: 919 855 3879

Micheala.Mitchell@dhhs.nc.gov

From: Leandro, Robert A. <robbleandro@parkerpoe.com>

Sent: Monday, March 17, 2025 7:04 PM

To: Mitchell, Micheala L < Micheala. Mitchell@dhhs.nc.gov>

Subject: [External] Cath Lab Replacement Notice

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Micheala,

Please see attached a Cath Lab Replacement Notice for our client DLP Cardiac Partners. Hope you are doing well. Let me know if you have any questions.

Robb Robert Leandro Partner Find our latest health care analysis here

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Office: 919.835.4636 | Fax: 919.834.4564 | map

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