

NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**  
Division of Health Service Regulation

ROY COOPER • Governor  
MANDY COHEN, MD, MPH • Secretary  
MARK PAYNE • Director

June 4, 2018

Robert A. Leandro  
301 Fayetteville Street, Suite 1400  
Raleigh, NC 27601

**No Review**

**Record #:** 2596  
**Facility Name:** Margaret R. Pardee Memorial Hospital  
**FID #:** 943324  
**Business Name:** Margaret R. Pardee Memorial Hospital  
**Business #:** 1176  
**Project Description:** Acquire hemodynamic system  
**County:** Henderson

Dear Mr. Leandro:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of May 29, 2018 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

However, you need to contact the Agency's Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

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: 2704 Mail Service Center, Raleigh, NC 27699-2704  
www.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

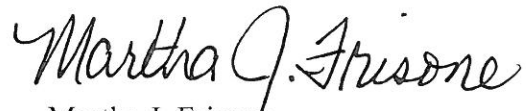
AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility ID # (FID) if the facility is licensed.

Sincerely,



Julie M. Faenza  
Project Analyst



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

cc: Amy Craddock, Assistant Chief, Healthcare Planning, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR



**Robert A. Leandro**  
*Partner*  
Telephone: 919.835.4636  
Direct Fax: 919.834.4564  
robbleandro@parkerpoe.com

Atlanta, GA  
Charleston, SC  
Charlotte, NC  
Columbia, SC  
Greenville, SC  
Raleigh, NC  
Spartanburg, SC

May 25, 2018

**VIA U.S. MAIL AND ELECTRONIC MAIL**

Martha Frisone, Chief  
Healthcare Planning and Certificate of Need Section  
North Carolina Department of Health and Human Services  
2704 Mail Service Center  
Raleigh, NC 27699-2704  
[Martha.Frisone@dhhs.nc.gov](mailto:Martha.Frisone@dhhs.nc.gov)



Re: *Acquisition of Hemodynamic System*

Dear Ms. Frisone:

As you are aware, DLP Cardiac Partners, LLC ("DLP Cardiac Partners") operates a Cardiac Catheterization Lab ("Cath Lab") at Pardee Hospital ("Pardee") in Hendersonville, North Carolina. DLP Cardiac Partners is authorized to own and operate the Cath Lab under North Carolina CON Law.

In 2016, DLP Cardiac Partners provided notice to the CON Section that it was replacing its Cath Lab equipment. One piece of equipment that it acquired as part of its Cath Lab replacement project was a GE MacLab, which is commonly referred to as a hemodynamic system. The purpose of a hemodynamic system is to measure and analyze data, such as blood flow and vital signs during a cardiac cath procedure. The hemodynamic system then automatically enters the data it has collected into procedure reports, the patient's electronic medical record ("EMR"), billing records, and other internal hospital documents. The data and auto-filling functions of the hemodynamic system serve to increase patient safety and operational efficiency by accurately gathering and transferring data across multiple platforms.

Unfortunately, the GE MacLab system purchased by DLP Cardiac Partners is not compatible with Pardee's electronic medical records system ("EMR"). As a result, the data recorded by the GE MacLab during each case is not automatically transferring to Pardee's EMR. In order to remedy this issue, Pardee has proposed acquiring a Philips XIM Hemodynamic System (the "Philips System"), which is compatible with Pardee's EMR. DLP Cardiac Partners will use Pardee's Philips System to collect and transfer patient data when it conducts Cath Lab procedures at the hospital. The cost of the Philips System will be approximately \$89,000.00. There are no construction or installation costs associated with acquiring the Philips System.

Pardee and DLP Cardiac Partners believe that the acquisition of the Philips System is exempt from certificate of need review because the primary purpose of the equipment is data processing. See N.C. Gen. Stat. § 131E-184(a)(3). Specifically, the system will be used to

PPAB 4260347v1

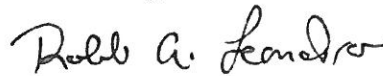
May 25, 2018  
Page 2

gather data during a case, process and analyze the data, and distribute the data across multiple electronic platforms.

Pardee and DLP Cardiac Partners have analyzed whether the acquisition of the Philips System would constitute a purchase of a "Major Medical Equipment," and thus would be subject to the CON law under N.C. Gen. Stat. §§ 131E-176(14a) and 178. We do not believe that the Philips System meets the definition of "Major Medical Equipment" because the approximate cost of the Philips System is \$89,000. Furthermore, the Philips Systems will not be used to provide medical or other health services, but instead will gather, process, and distribute data across platforms.

Please confirm that the Agency agrees with our assessment and that the above acquisition does not require CON approval. I greatly appreciate your attention to this matter. If you have any questions, please feel free to contact me directly.

Sincerely,

A handwritten signature in cursive script that reads "Robb A. Leandro".

Robb Leandro