



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

December 1, 2021

John G. Green  
kivey@pda-inc.net (on behalf of John G. Green)

**Exempt from Review – Replacement Equipment**

**Record #:** 3750  
**Date of Request:** November 24, 2021  
**Facility Name:** Iredell Memorial Hospital  
**FID #:** 933284  
**Business Name:** Iredell Health System  
**Business #:** 2523  
**Project Description:** Replace existing cardiac catheterization equipment  
**County:** Iredell

Dear Mr. Green:

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 Siemens Artis to replace the Phillips Healthcare Allura Xper FD10. 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,

Julie M. Faenza  
Project Analyst

Micheala Mitchell  
Chief

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



November 24, 2021

Ms. Lisa Pittman  
Assistant Chief, Healthcare Planning and Certificate of Need Section  
Celia Inman CON Analyst  
Division of Health Service Regulation/ DHSR  
809 Ruggles Drive  
Raleigh, NC 27603  
misty.piekaar@dhhs.nc.gov

RE: Exemption from CON Review and Determination of Non-Reviewability to Replace Angiography Equipment, Iredell Memorial Hospital, Statesville, Iredell County, CON No. F- 7268-05, FID 933284

Dear Ms. Frisone and Ms. Piekaar:

As required by NCGS 131E-184(a), this letter provides notice to the North Carolina Department of Health and Human Services, Division of Health Service Regulation ("DHSR"), Certificate of Need Section ("Agency") that Iredell Health intends to replace 10-year-old cardiac catheterization equipment located at Iredell Memorial Hospital. The original equipment was grandfathered, but the current equipment has been in continuous service. As noted in the Siemen's offer, the purchase and installation date were delayed by COVID-19. The vendor has not increased the price.

The project meets the requirements of both Replacement Equipment at NCGS-131E-176(22a) and Exemption for replacement equipment at NCGS 131E-184(g).

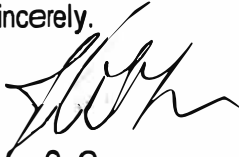
- The replacement equipment will be purchased refurbished and cost less than \$2,000,000 including required renovations and installation.
- The project will replace equipment that is in service and has been in continuous service for at least three years.
- The project will not increase the cost or charges of the angiography service by more than 10 percent.
- The existing equipment, a Phillips Allura Xper FD 10 with serial number 1798, will be removed from service and returned to the vendor as trade-in on the new equipment.
- The replacement will be located on the main campus of the hospital in the main hospital building in which the hospital provides clinical activities and exercises financial and administrative control. The angiography suite is on the second floor of the main Iredell Memorial Hospital building.

The replacement is necessary because the 10-year-old equipment has an increasing maintenance history, is at the end of its useful life, and is not upgradeable.

The project will not require any renovation or other changes to Iredell Memorial Hospital.

We are requesting that the Agency confirm that the proposed changes are exempt from review under the CON law's exemption provisions in N.C. Gen. Stat. § 131E-184(g).

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Green', written over the word 'Sincerely,'.

John G. Green  
President and CEO

Attachments:

- Exhibit A - Vendor Quote with Trade in and Construction Estimate Revals
- Exhibit B - Proposed Total Capital Cost of Project
- Exhibit C - Existing/Replacement Equipment Comparison

F:\Client Projects\Iredell 2012 ff\Iredell 21\Cardiac Cath Replacement #2\Exemption LTR Siemens replace2 For Signature.docx



Siemens Medical Solutions USA, Inc.  
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE  
Mathew Hayes  
mathew.hayes@siemens-healthineers.com

Customer Number: 0000007077

Date: 09/17/2020

IREDELL MEMORIAL HOSPITAL  
557 BROOKDALE DR  
STATESVILLE, NC 28677

Siemens Medical Solutions USA, Inc. is pleased to submit the following quotation for the products and services described herein at the stated prices and terms, subject to your acceptance of the terms and conditions on the face and back hereof, and on any attachment hereto.

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**Contract Total: \$ 529,500.00**  
*(total does not include any Optional or Alternate components which may be selected)*

Proposal valid until 09/30/2020

Estimated Delivery Date: 3/2021

Delivery dates and other contractual obligations of Seller may change due to the effects of the Covid-19 epidemic or other epidemic, including delays and disruptions in the supply chain, manufacturing, or execution as well orders by authorities and prioritization of (new and existing) orders of customers which are essential for the public healthcare. The magnitude of such changes cannot be predicted and might be substantial because it depends on the development of the Covid-19 epidemic or other epidemic.

This proposal includes the trade-in of equipment referenced in Trade Sheet Project 2020-2067.

This offer is only valid if a firm, non-contingent order is placed with Siemens and a signed POS contract must accompany the equipment order.

This offer is only valid if firm, non-contingent orders for the following quotes are simultaneously placed with Siemens:  
CPQ-209871  
CPQ-220264

Accepted and Agreed to by:

Siemens Medical Solutions USA Inc.

IREDELL MEMORIAL HOSPITAL

By (sign): \_\_\_\_\_

By (sign): 

Name: Mathew Hayes

Name: Joshua Self

Title: \_\_\_\_\_

Title: VP Operations


## PROPOSED CAPITAL COSTS

Project name: Replacement of Philips Allura Xper FD10 cardiac catheterization equipment

Proponent: Iredell Health

Building Purchase Price	
Purchase Price of Land	
Closing Costs	
Site Preparation	
Construction/Renovation Contract(s)	\$187,722
Landscaping	
Architect / Engineering Fees	NA design build
Medical Equipment	\$529,500
Non-Medical Equipment	0
Furniture	0
Consultant Fees (Physicist calibration + Rigging)	+16,022
Financing Costs	0
Interest during Construction	0
Other (specify) Contingency	\$10,000
Total Capital Cost	\$743,244

I assure that, to the best of my knowledge, the above capital costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

  
 \_\_\_\_\_  
 John G. Green  
 President and CEO

11/24/2020  
 \_\_\_\_\_  
 Date

**EQUIPMENT COMPARISON for REPLACEMENT EQUIPMENT EXEMPTION**

**Exhibit C**

	<b>EXISTING EQUIPMENT</b>	<b>REPLACEMENT EQUIPMENT</b>
Type of Equipment (List Each Component)	Angiography	Angiography
Manufacturer of Equipment	Phillips Healthcare	Siemens
Tesla Rating for MRIs	NA	NA
Model Number	9896-002-00542	ARTIS
Serial Number	1798	
Provider's Method of Identifying Equipment	Allura Xper FD10	Artis Cath Lab
Specify if Mobile or Fixed	fixed	fixed
Mobile Trailer Serial Number/VIN#	NA	NA
Mobile Tractor Serial Number/VIN#	NA	NA
Date of Acquisition of Each Component	2007	2021
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	new	new
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	\$2,968,794	See form Exhibit B
Total Cost of Equipment	\$1,213,197	\$529,500
Fair Market Value of Equipment	\$7,750 (2021 trade-in value)	\$529,500
Net Purchase Price of Equipment		\$529,500
Locations Where Operated	Iredell Memorial Hospital	Iredell Memorial Hospital
Number Days in Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)		<10%
Percent of Change in Per Procedure Operating Expenses (by Procedure)		<10%
Type of Procedures Currently Performed on Existing Equipment	Cardiac Cath	
Type of Procedures New Equipment is Capable of Performing	Cardiac Cath/ vascular	Cardiac Cath

**From:** [Inman, Celia C](#)  
**To:** [Waller, Martha K](#)  
**Subject:** Fw: [External] Exemption Request: Iredell Health System  
**Date:** Wednesday, November 24, 2021 11:48:06 AM  
**Attachments:** [Iredell Health System Exemption Request Angio.pdf](#)

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Please log this exemption request.

Celia C. Inman  
N.C. Department of Health and Human Services  
Project Analyst, CON Section - Division of Health Service Regulation  
809 Ruggles Drive  
Raleigh, NC 27603  
(Office) [919-855-3873](tel:919-855-3873)  
[celia.inman@dhhs.nc.gov](mailto:celia.inman@dhhs.nc.gov)  
[www.ncdhhs.gov/dhsr](http://www.ncdhhs.gov/dhsr)

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**From:** Kelly Ivey <kivey@pda-inc.net>  
**Sent:** Wednesday, November 24, 2021 11:02 AM  
**To:** Inman, Celia C <celia.inman@dhhs.nc.gov>  
**Cc:** Nancy Lane <nlane@pda-inc.net>; Skip Meador <Skip.Meador@iredellhealth.org>; Avis Little <Avis.Little@iredellhealth.org>  
**Subject:** [External] Exemption Request: Iredell Health System

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

Celia,

Attached is an exemption from CON review request for Iredell Health System to replace its angiography equipment. Please respond to this email as confirmation of receipt.

Let me know if you have any questions or need additional information.

Thanks and Happy Thanksgiving,  
Kelly

*Kelly Ivey*  
[kivey@pda-inc.net](mailto:kivey@pda-inc.net)  
919.754.0303  
[www.pdaconsultants.com](http://www.pdaconsultants.com)

# PDA



*Take a Problem, Make it a Feature.*

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