



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

JOSH STEIN • Governor

DEVDUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

May 7, 2025

Joanie S. King

jking@carterethealth.org

No Review

Record #: 4752

Date of Request: April 4, 2025

Facility Name: Carteret General Hospital

FID #: 923076

Business Name: Carteret County General Hospital Corporation

Business #: 418

Project Description: Acquire Intuitive IS5000 da Vinci V surgical robot system

County: Carteret

Dear Ms. King:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the representation in your request and the CON law **in effect on the date of this response to your request**, the project as described is not governed by, and therefore, does not currently require a certificate of need. 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.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. **As a reminder, it is unlawful to offer or develop a new institutional health service without first obtaining a certificate of need. The Department reserves the right to impose sanctions, including civil penalties and the revocation of a license, upon any entity that offers or develops a new institutional health service without first obtaining a certificate of need.**

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

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Please do not hesitate to contact this office if you have any questions.

Sincerely,



Gregory F. Yakaboski
Project Analyst



Micheala Mitchell
Chief

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

April 3, 2025

VIA ELECTRONIC MAIL

Mr. Greg Yakaboski
Healthcare Planning and Certificate of Need Section Division of Health Service Regulation
NC Department of Health and Human Services
Greg.Yakaboski@dhhs.nc.gov
RE: No Review Determination -

Dear Mr. Yakaboski:

On behalf of Carteret County Hospital Corporation, this letter serves as notice to the Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section ("Agency") that Carteret County Hospital Corporation intends to acquire an Intuitive da Vinci V surgical robot to be located in Carteret County Hospital surgical suite in Morehead City, North Carolina. The details regarding the DaVinci V robot system are set forth below.

The purpose of this letter is to request that the Agency issue a "No Determination Letter" indicating the acquisition of the da Vinci system is not subject to CON Section review and does not require that the Hospital obtain a certificate of need ("CON").

The da Vinci V system purchase cost will be \$2,000,000. The equipment requires no modifications to the building and there are no construction costs involved. Further, the addition does not constitute a new institutional health service.

Carteret respectfully requests that you confirm in writing that the acquisition does not require a CON. Please do not hesitate to contact me at jsking@carterethealth.org if you require any additional information.

Respectively,



Joanie S. King
Chief Financial Officer
Carteret County General Hospital Corporation
Attachment



MARK SHOUSE | CHAIRMAN
KYLE MAREK | PRESIDENT

3500 ARENDELL ST. | MOREHEAD CITY, NC 28557
P | 252.499.6000

CARTERETHEALTH.ORG

Annex 1 to Transaction Agreement – Products and Price

1. System Description

Intuitive will provide the following to Participant:

da Vinci S[®] Single Console System (Fluorescence Imaging Included)

One (1): da Vinci S[®] System Console

One (1): da Vinci S[®] System Tower

One (1): Integrated Intuitive HUB

One (1): Integrated Insufflator

One (1): Integrated E-200 Generator

One (1): CO₂ Tank Kit

One (1): da Vinci S[®] System Patient Cart

One (1): da Vinci S[®] Operating System Software Package (including Integrated Table Motion)

Warranty period: One (1) year from the Acceptance

Vision Equipment

One (1): NIR Handheld Camera Control Unit

One (1): NIR Handheld Camera Light Source

One (1): NIR Handheld Camera

Two (2): da Vinci S[®] Endoscope, 0°

Two (2): da Vinci S[®] Endoscope, 30°

Four (4): da Vinci S[®] Endoscope Trays

One (1): NIR Handheld Reprocessing Tray

Warranty period: One (1) year from the Acceptance

Accessories

One (1): Box of 10 Tip Cover Accessory (For use with Endowrist Monopolar Curved Scissors)

Three (3): Monopolar Cautery Cord

Three (3): Bipolar Cautery Cord

Eight (8): 8 mm Hex Cannula, standard

Two (2): Box of 6 8 mm Bladeless Retractor

Four (4): Box of 10 Universal Seal (5-12mm)

One (1): Box of 3 8mm Gage Pin

Two (2): Pack of 20 Instrument Arm Drape

One (1): Pack of 20 Column Drape

Three (3): 8mm Instrument Introducer

Two (2): 12mm Stapler Cannula

Two (2): Box of 6 Da Vinci Insufflator Tube Set - Smoke Evacuation

One (1): NIR Handheld Camera Light Guide

One (1): Light Guide Adapter for Schoelly and Storz endoscopes

One (1): Laparoscope 10mm, 0°, NIR

One (1): Laparoscope 10mm, 30°, NIR

One (1): Laparoscope 5mm, 0°

One (1): Laparoscope 5mm, 30°

Warranty period: 90 days from Acceptance

Training Instruments

One (1): Monopolar Curved Scissors, Training

One (1): Force Bipolar, Training

One (1): Large Needle Driver, Training

One (1): Mega SutureCut Needle Driver, Training

One (1): Cadaver Forceps, Training

Warranty period: 90 days from Acceptance

da Vinci S[®] System Documentation

One (1): Da Vinci S System User Manual

One (1): E-200 User Manual

One (1): Insufflator Tube Set User Manual

One (1): Force Feedback User Manual

One (1): Integrated table Motion, Quick Reference Guide - Bedside

One (1): Integrated Table Motion, Quick Reference Guide - Anesthesia

One (1): Reprocessing Wall Chart Kit

One (1): Cleaning and Sterilization Kit

One (1): US Language Kit

One (1): Da Vinci S Representative Adult Uses System User Manual Addendum

One (1): Da Vinci S SynchroSeal Instruments and Accessories User Manual Addendum

One (1): SureForm 45 and SureForm 60 Instruments and Accessories User Manual Addendum

One (1): SureForm 45 and SureForm 60 Force Fire, FDA Guidance

One (1): NIR Camera System User Manual Addendum

One (1): Universal Reprocessing Hardware kit

Two (2): Endowrist Instrument Release Kit (IRK)

Warranty period: n/a

Upgrades with Incremental Costs

One (1): Backup E-200 Kit (plus service)

Warranty period: One (1) year from the Acceptance

(all kits subject to change without notice)

2. Pricing and Products.

Part Number	Qty	Item	Price
System:			
	1	IS5000 DA VINCI SYSTEM	\$2,000,000.00
Upgrade:			
	1	INTUITIVE HUB	\$0.00
	1	Da Vinci E-200 Generator (Backup)	\$0.00
Freight			
	1	System Freight - East (AL, CT, DC, DE, FL, GA, IN, KY, MA, MD, ME, MI, MS, NC, NH, NJ, NY, OH, PA, RI, TN, SC, VA, VT, WV)	\$0.00
Total			\$2,000,000.00

Description	Platform	IdA Credit
IS5000 DA VINCI SYSTEM	da Vinci S	\$50,000.00

Products listed above are subject to availability and, as applicable, subject to the then current terms and conditions of the da Vinci® Instrument & Accessory Catalog and/or intuitive.com/digital-solutions-terms as if such terms were contained in this Agreement. Delivery charges will be Pre-Pay & Add. Instrument OR Accessories will be shipped FCA Intuitive's warehouse. If Single Site Instruments are listed, they will be delivered upon Participant's completion of the advanced instrument training verification.

The da Vinci S® Placed System's integrated Intuitive Hub will be activated during the first major Software upgrade for the System (currently known as Pl 2). Intuitive will deliver a non-integrated Intuitive Hub with the da Vinci S® Placed System for Customer to use until the integrated Intuitive Hub is activated. After the integrated Intuitive Hub is activated, Customer will have the option to either return the non-integrated Intuitive Hub to Intuitive and opt out of the Service for the non-integrated Intuitive Hub or keep the non-integrated Intuitive Hub and enter into a separate Service agreement for that non-integrated Intuitive Hub. Additionally, Intuitive will deliver and install the SimNow® Simulator after the first major Software upgrade for the System.

Intuitive makes no representation with regard to Certificate of Need requirements for this purchase. It is Participant's responsibility to determine whether this purchase complies with Participant's State Certificate of Need law and what Certificate of Need filing, if any, needs to be made with regard to this purchase.

3. **Acceptance.** The System is deemed accepted by Participant upon delivery at Participant's designated location ("Acceptance").
4. **Delivery date.** The estimated delivery date for the System is 03/31/2025 ("Delivery Date"). The Delivery Date is an estimated and non-binding "on or before" delivery date to the Participant's designated location (see "Ship-to" below).
5. **The "Ship-To" information for Participant is:**

Carteret General Hospital
3500 Arendell St.
Morehead City, North Carolina, 28557-2901

6. **The "Bill-To" information for Participant is:**

Carteret General Hospital
3500 Arendell St.
Morehead City, North Carolina, 28557-2901
Participant's PO Number: _____

From: [Yakaboski, Greg](#)
To: [Stancil, Tiffany C](#)
Subject: FW: [External] Carteret - da Vinci equipment
Date: Thursday, April 3, 2025 4:34:30 PM
Attachments: [Carteret da Vinci V letter of no review.pdf](#)

Hey Tiffany,

Just received this No Review Request.

Thanks,
Greg

Sincerely,

Gregory F. Yakaboski

Gregory F. Yakaboski
Project Analyst
[Division of Health Service Regulation](#), Certificate of Need
[NC Department of Health and Human Services](#)

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Office: 919-855-3873
Greg.Yakaboski@dhhs.nc.gov

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Raleigh, NC 27699-2704

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From: Joanie King <jsking@carterethealth.org>
Sent: Thursday, April 3, 2025 4:07 PM
To: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>
Cc: Kyle Marek <kmarek@carterethealth.org>
Subject: [External] Carteret - da Vinci equipment

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, Greg - please see the attached and advise of any questions.

Thank you,
Joanie



Joanie King

CFO/Vice President Fiscal Services
Carteret Health Care
3500 Arendell Street, Morehead City, North Carolina 28557
Office: 252-499-6104 | jking@CarteretHealth.org

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