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

January 12, 2021

Denise M. Gunter
Denise.gunter@nelsonmullins.com

Exempt from Review – Replacement Equipment

Record #:	**3467**
Date of Request:	December 23, 2020
Facility Name:	FirstHealth Moore Regional Hospital
FID #:	943358
Business Name:	FirstHealth of the Carolinas, Inc.
Business #:	737
Project Description:	Replace existing da Vinci surgical robot
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 Da Vinci Xl/TruSystem 7000dV Da Vinci surgical robot to replace the existing Da Vinci Sl surgical robot. 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

Lisa Pittman
Assistant Chief, Certificate of Need

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

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December 23, 2020

VIA EMAIL

Martha J. Frisone, Chief
Healthcare Planning and Certificate of Need Section
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Edgerton Building
809 Ruggles Drive
Raleigh, North Carolina 27603

Re:	Facility Name:	FirstHealth Moore Regional Hospital
	FID#	943358
	Business Name:	FirstHealth of the Carolinas, Inc.
	Business#	727
	HSA:	V
	Project Description:	Replace Existing da Vinci surgical robot
	County:	Moore

Dear Ms. Frisone:

Pursuant to N.C. Gen. Stat. § 131E-184(a)(7), this letter provides prior written notice to the Agency that FirstHealth Moore Regional Hospital ("FMRH") intends to replace a da Vinci surgical robot on the main campus of FMRH at a cost of less than $2 million.

Background

FMRH currently operates one da Vinci surgical robot, a da Vinci SI, on its main campus (the "Existing Unit"). The Existing Unit, which was purchased new, was acquired on April 18, 2012. The Existing Unit is at the end of its useful life, and FirstHealth has decided to replace the Existing Unit with a new da Vinci Xi unit (the "Replacement Unit"). The Replacement Unit will also be used on the main campus in OR #3 of FMRH. Robotic surgery offers patients a number of benefits including more precise surgery, shorter recovery time, less pain and shorter hospital stays. Replacing the Existing Unit with a

new, state-of-the-art Replacement Unit is essential in order for FMRH to care for the surgical patients who choose FMRH for their care and can benefit from robotic surgery.

The total cost of the Replacement Unit is $808,658.82. This includes the cost of a TruSystem Table Package. The TruSystem is designed to work with integrated table motion for the da Vinci Xi surgical system so that the patient can be dynamically positioned while the surgeon operates. No construction will be necessary to make the Replacement Unit operational. When the Replacement Unit is installed, the Existing Unit will be removed from North Carolina. A copy of the Equipment Comparison Form is attached as **Exhibit A**, and the Capital Cost Form is attached as **Exhibit B**. **Exhibit C** contains the list of surgical procedures that both the Existing Unit and the Replacement Unit are capable of doing, as referenced in **Exhibit A**.

Analysis

N.C. Gen. Stat. § 131E-184(a)(7) exempts the acquisition of "replacement equipment" upon prior written notice to the Agency. This exemption has a $2 million capital cost limit.

Replacement equipment is defined as:

> . . . [E]quipment that costs less than two million ($2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. In determining whether the replacement equipment costs less than two million dollars ($2,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

N.C. Gen. Stat. § 131E-176(22a).

Pursuant to 10A NCAC 14C .0303(c), "comparable medical equipment" means "equipment which is functionally similar and which is used for the same diagnostic or treatment purposes." The rule further provides:

> (d) Replacement equipment is comparable to the equipment being replaced if:

> (1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
> (2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
> (3) the acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

10A NCAC 14C.0303(d)(1)-(3).

The Existing Unit is currently in use at FMRH. The proposed Replacement Unit is functionally similar to the Existing Unit. The Existing Unit and the Replacement Unit are used for the same diagnostic and treatment purposes. *See* **Exhibit C**. The Replacement Unit will not be used to provide a new health service, though it does possess expanded capabilities due to technological improvements. The Existing Unit will be removed from North Carolina when the Replacement Unit is installed. The acquisition of the Replacement Unit will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired. None of the exclusions contained in 10A NCAC 14C .0303(e) applies here. *See also* **Exhibit A**, the Equipment Comparison Form.

As documented in **Exhibit B**, the Capital Cost Form, the cost of the project is less than $2 million.[1] This includes the cost of all activities necessary to make the equipment operational.

Conclusion

For the above-stated reasons, FMRH respectfully requests that it be allowed to replace the Existing Unit with the Replacement Unit on the main campus of FMRH.

Thank you for your time and consideration. If you have any questions or need additional information, please let me know.

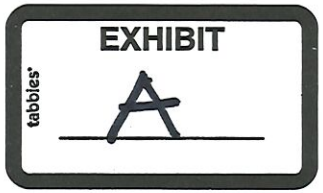
[1] Even if the cost of this project exceeded $2 million, it would still be exempt from CON review pursuant to the Main Campus Exemption. *See* N.C. Gen. Stat. § 131E-184(f).

With best personal regards.

Sincerely,

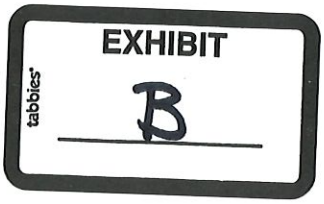
Denise M. Gunter

Enclosures



EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	Da Vinci Robot	Da Vinci Robot & TruSystem Table Package
Manufacturer	Intuitive	Intuitive & Hill-Rom
Model number	Da Vinci SI	Da Vinci XI / TruSystem 7000dV
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	SH1204	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	4/18/2012	12/15/2020
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>	NA	$808,658.82
Total cost of the equipment	$735,000	$808,658.82
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	OR #3	OR #3
Document that the existing equipment is currently in use	See Attached	NA
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	NA	NA
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	NA	NA
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	See Attached	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	See Attached



Projected Capital Cost Form

Building Purchase Price	
Purchase Price of Land	
Closing Costs	
Site Preparation	
Construction/Renovation Contract(s)	
Landscaping	
Architect / Engineering Fees	
Medical Equipment	$808,658.82
Non-Medical Equipment	
Furniture	
Consultant Fees (specify)	
Financing Costs	
Interest during Construction	
Other (specify)	
Total Capital Cost	$808,658.82

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.

_____ Date Signed:_____

Signature of Licensed Architect or Engineer

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.

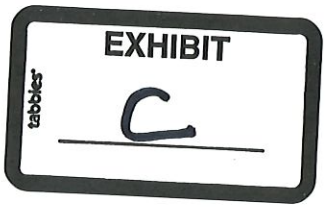
_____ Date Signed: 12/22/2020

Signature of Officer/Agent

CEO / Mickey W. Foster

Title of Officer/Agent

Date of Last Revision: 5.17.19



PRIN PROC DESC
BRNCHSC BRUSHING/PROTECTED BRUSHINGS
BRNCHSC EBUS GUIDED SAMPL 1/2 NODE STATION/STRUX
BRNCHSC EBUS GUIDED SAMPL 3/> NODE STATION/STRUX
BRNCHSC INCL FLUOR GDNCE DX W/CELL WASHG SPX
BRNCHSC W/TRACHEAL/BRONCHIAL DILAT/CLSD RDCTJ FX
BRONCHOSCOPY BRONCHIAL/ENDOBRNCL BX 1+ SITES
BRONCHOSCOPY NEEDLE BX TRACHEA MAIN STEM&/BRON
BRONCHOSCOPY W/PLMT FIDUCIAL MARKERS SINGLE/MULT
BRONCHOSCOPY W/TRANSBRONCHIAL LUNG BX 1 LOBE
Bypass Ileum to Cutaneous, Open Approach
Bypass Ileum to Cutaneous, Percutaneous Endoscopic Approach
Bypass Sigmoid Colon to Cutaneous, Perc Endo Approach
Bypass Trachea to Cutaneous with Trach Dev, Open Approach
Control Bleeding in Genitourinary Tract, Perc Endo Approach
Excision of Bladder Neck, Percutaneous Endoscopic Approach
Excision of Bladder, Percutaneous Endoscopic Approach
Excision of Cecum, Percutaneous Endoscopic Approach
Excision of Descending Colon, Perc Endo Approach
Excision of Ileum, Open Approach
Excision of Large Intestine, Open Approach
Excision of Large Intestine, Perc Endo Approach
Excision of Left Kidney, Percutaneous Endoscopic Approach
Excision of Left Lower Lung Lobe, Endo, Diagn
Excision of Left Lower Lung Lobe, Open Approach
Excision of Left Lower Lung Lobe, Perc Endo Approach
Excision of Left Upper Lung Lobe, Endo, Diagn
Excision of Left Upper Lung Lobe, Open Approach
Excision of Pelvis Lymphatic, Perc Endo Approach
Excision of Pelvis Lymphatic, Perc Endo Approach, Diagn
Excision of Rectum, Percutaneous Endoscopic Approach
Excision of Right Lower Lung Lobe, Perc Endo Approach
Excision of Right Middle Lung Lobe, Perc Endo Approach
Excision of Right Upper Lung Lobe, Perc Endo Approach
Excision of Sigmoid Colon, Open Approach
Excision of Sigmoid Colon, Percutaneous Endoscopic Approach
Excision of Small Intestine, Open Approach
Excision of Transverse Colon, Perc Endo Approach
Extraction of Left Upper Lung Lobe, Endo, Diagn
Inspection of Prostate/Seminal Ves, Perc Endo Approach
Inspection of Right Lung, Percutaneous Endoscopic Approach
Inspection of Upper Intestinal Tract, Perc Endo Approach
LAP RPR HRNA XCPT INCAL/INGUN NCRC8/STRANGULATED
LAPAROSCOPY COLPOPEXY SUSPENSION VAGINAL APEX
LAPAROSCOPY REPAIR INCISIONAL HERNIA REDUCIBLE
LAPAROSCOPY SURG ABLATION RENAL CYSTS
LAPAROSCOPY SURG PARTIAL NEPHRECTOMY

LAPAROSCOPY SURG RPR INITIAL INGUINAL HERNIA
LAPAROSCOPY SURG W/BX SINGLE/MULTIPLE
LAPAROSCOPY TOT HYSTERECTOMY >250 G W/TUBE/OVAR
LAPAROSCOPY W TOTAL HYSTERECTOMY UTERUS 250 GM/<
LAPAROSCOPY W/LYSIS OF ADHESIONS
LAPAROSCOPY W/RMVL ADNEXAL STRUCTURES
LAPS ABLTJ RENAL MASS LESION W/INTRAOP US
LAPS BI TOT PEL LMPHADEC & PRI-AORTIC LYMPH BX 1
LAPS FULG/EXC OVARY VISCERA/PERITONEAL SURFACE
LAPS MYOMECTOMY EXC 1-4 MYOMAS 250 GM/<
LAPS MYOMECTOMY EXC 5/> MYOMAS >250 GRAMS
LAPS REPAIR HERNIA EXCEPT INCAL/INGUN REDUCIBLE
LAPS RPR INCISIONAL HERNIA NCRC8/STRANGULATED
LAPS RPR PARAESPHGL HRNA INCL FUNDPLSTY W/MESH
LAPS RPR RECURRENT INCAL HRNA NCRC8/STRANGULATED
LAPS RPR RECURRENT INCISIONAL HERNIA REDUCIBLE
LAPS SUPRACRV HYSTEREC >250 G RMVL TUBE/OVARY
LAPS SURG BILATERAL TOTAL PELVIC LMPHADECTOMY
LAPS SURG ESOPG/GSTR FUNDOPLASTY
LAPS SURG RPR RECURRENT INGUINAL HERNIA
LAPS TOTAL HYSTERECT 250 GM/< W/RMVL TUBE/OVARY
LAPS W/BI TOT PEL LMPHADEC & OMNTC LYMPH BX
Release Ileum, Open Approach
Release Omentum, Percutaneous Endoscopic Approach
Release Peritoneum, Percutaneous Endoscopic Approach
Release Small Intestine, Percutaneous Endoscopic Approach
Repair Abdominal Wall, Open Approach
Repair Bladder, Percutaneous Endoscopic Approach
Repair Descending Colon, Open Approach
Repair Rectum, Percutaneous Endoscopic Approach
Repair Right Kidney Pelvis, Percutaneous Endoscopic Approach
Repair Transverse Colon, Open Approach
Repair Transverse Colon, Percutaneous Endoscopic Approach
Reposition Rectum, Open Approach
Reposition Rectum, Percutaneous Endoscopic Approach
Reposition Vagina, Percutaneous Endoscopic Approach
Resection of Aortic Lymphatic, Perc Endo Approach
Resection of Ascending Colon, Perc Endo Approach
Resection of Bilateral Fallopian Tubes, Perc Endo Approach
Resection of Bilateral Ovaries, Perc Endo Approach
Resection of Cecum, Open Approach
Resection of Descending Colon, Perc Endo Approach
Resection of Left Kidney, Percutaneous Endoscopic Approach
Resection of Left Lower Lung Lobe, Perc Endo Approach
Resection of Left Upper Lung Lobe, Open Approach
Resection of Left Upper Lung Lobe, Perc Endo Approach
Resection of Pelvis Lymphatic, Perc Endo Approach

Resection of Prostate, Percutaneous Endoscopic Approach
Resection of Rectum, Percutaneous Endoscopic Approach
Resection of Right Fallopian Tube, Perc Endo Approach
Resection of Right Kidney, Open Approach
Resection of Right Kidney, Percutaneous Endoscopic Approach
Resection of Right Large Intestine, Open Approach
Resection of Right Large Intestine, Perc Endo Approach
Resection of Right Lower Lobe Bronchus, Perc Endo Approach
Resection of Right Lower Lung Lobe, Perc Endo Approach
Resection of Right Middle Lobe Bronchus, Perc Endo Approach
Resection of Right Middle Lung Lobe, Perc Endo Approach
Resection of Right Upper Lung Lobe, Perc Endo Approach
Resection of Sigmoid Colon, Open Approach
Resection of Sigmoid Colon, Percutaneous Endoscopic Approach
Resection of Sigmoid Colon, Via Opening w Perc Endo
Resection of Uterus, Open Approach
Resection of Uterus, Percutaneous Endoscopic Approach
Resection of Uterus, Supracervical, Perc Endo Approach
Resection of Uterus, Via Natural or Artificial Opening
Resection of Uterus, Via Opening w Perc Endo
RPR 1ST INGUN HRNA AGE 5 YRS/> REDUCIBLE
Supplement Abdominal Wall with Synth Sub, Perc Endo Approach
Supplement Diaphragm with Nonaut Sub, Perc Endo Approach
Supplement Diaphragm with Synth Sub, Perc Endo Approach
Supplement L Inguinal Region w Synth Sub, Perc Endo
UNLISTED LAPAROSCOPIC PROCEDURE STOMACH
UNLISTED LAPAROSCOPY PROCEDURE BLADDER
UNLISTED LAPAROSCOPY PROCEDURE SPLEEN
Grand Total