



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

April 16, 2021

Kenneth Burgess
kburgess@poynerspruill.com

Exempt from Review – Replacement Equipment

Record #: 3515
Date of Request: March 26, 2021
Facility Name: Mission Hospital
FID #: 943349
Business Name: MH Mission Hospital, LLLP
Business #: 3045
Project Description: Replace existing DaVinci surgical robotic system
County: Buncombe

Dear Mr. Burgess:

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 DaVinci Xi Dual Console Surgical Robotic System to replace the IS3000 DaVinci Si Surgical Robotic System. 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

Lisa Pittman
Acting Chief, Certificate of Need

cc: Acute and Home Care Licensure & Certification 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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

March 26, 2021

Kenneth L. Burgess
Partner
D: 919.783.2917
F: 252.972.7045
kburgess@poynerspruill.com

VIA EMAIL

Lisa Pittman, Assistant Chief
Healthcare Planning and Certificate of Need Section
N.C. Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603
Via Email to: Lisa.Pittman@dhhs.nc.gov

RE: *MH Mission Hospital, LLLP Notice of Exemption for Replacement of DaVinci Surgical Robotic System; FDID # 943349*

Dear Lisa:

Our law firm represents MH Mission Hospital, LLLP ("Mission"), which owns and operates an Intuitive DaVinci Surgical Robotic System that currently is located in the Surgical Suite at the hospital's main building on the main campus at 509 Biltmore Avenue, Asheville, North Carolina. Mission now desires to replace the existing DaVinci System. I am writing to request that the N.C. Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section ("the CON Section") confirm that the replacement of the DaVinci System on the Mission main campus is exempt from certificate of need ("CON") review within the meaning of N.C. Gen. Stat. §131E-184(a)(7).

Mission proposes to replace its existing IS3000 DaVinci System with a new DaVinci Xi Dual Console System. See **Exhibit 1** (Letter from M. Giuffrida, Intuitive Surgical, Inc.) and **Exhibit 2** (Letter from Mission's Chief Operating Officer reflecting existing and replacement system descriptions). All of Mission's current robotics surgical systems are located in the K Tower in the main hospital building on Mission's main campus at 509 Biltmore Avenue in Asheville, North Carolina. The existing IS3000 DaVinci System is currently located there and the replacement DaVinci Xi Dual Console System will also be located in the K Tower and, specifically, in Operating Room # 32.

For the reasons set forth below, we believe that Mission's replacement of the existing DaVinci System is exempt from CON review pursuant to N.C. Gen. Stat. §131E-184(a)(7).

Analysis

The CON Law precludes any person from offering or developing a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178(a). The definition of "new institutional health service" includes, *inter alia*, the following:

- The acquisition by purchase, donation, lease, transfer or comparable arrangement of "major medical equipment," which is defined as a single unit or single system of components used to provide medical and health services which costs more than \$750,000.00, including the costs of the equipment and all studies, drawings, installation and any other activities essential to acquiring and making the equipment operational.

N.C. Gen. Stat. §§ 131E-176(16)(p) and (14o). However, the CON Law contains a specific exemption applicable to "replacement equipment" that costs less than \$2,000,000.00.

Statutory Exemption For Replacement Equipment Which Costs Less Than \$2,000,000.00

N.C. Gen. Stat. §131E-184(a)(7) provides an express exemption from CON review for the acquisition and installation of "replacement equipment" costing less than \$2,000,000.00, provided that the CON Section receives prior written notice from the party proposing to acquire the equipment which explains why the proposed acquisition and installation qualifies under this exemption. The statute and accompanying regulations further define "replacement equipment" as follows:

Equipment that costs less than two million dollars (\$2,000,000.00) 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 calculating the total cost of the replacement equipment, the costs of the 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 or the cost of the equipment, whichever is greater.

N.C. Gen. Stat. §131E-176(22a). 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 N.C. Admin. Code 14C .0303(d)(1)-(3).¹

Replacement Of Mission's DaVinci Surgical Robotic System Is Exempt From CON Review Under These Authorities

The replacement of Mission's DaVinci System falls within the parameters of this exemption because:

1. The equipment being replaced is currently situated in the K Tower Surgical Suite which is located in the hospital's main building located at 509 Biltmore Avenue, Asheville, North Carolina, on the hospital's main campus. The replacement DaVinci System will be situated at precisely the same location as the existing DaVinci System. See **Exhibit 2** (letter from Mission's Chief Operating Officer).

¹ Pursuant to 10A NCAC 14C .0303(e), equipment does not qualify as "replacement equipment" where equipment which was second-hand or reconditioned is being replaced with new equipment within three (3) years of the acquisition of the equipment being replaced, or leased equipment is being replaced with purchased equipment. The existing DaVinci System which is being upgraded was new when it was purchased by Mission. As such, 10A NCAC 14C .0303(e) does not apply to this Project.

2. The equipment being replaced is currently in use at Mission. See **Exhibit 2** (letter from Mission's Chief Operating Officer).
3. The total estimated cost of the project is \$1,671,829.41,² placing the project within the terms of the statutory exception set forth at N.C. Gen. Stat. §131E-184(a)(7). See **Exhibit 3** (affidavit from Mission's Chief Operating Officer attesting to the total estimated costs of the replacement DaVinci system)³ and **Exhibit 4** (Projected Capital Cost Form).
4. The replacement DaVinci System will be acquired pursuant to a capital lease which the CON Statute essentially treats as a purchase. N.C. Gen. Stat. section 131E-176(2)(d) and 10A NCAC 14C .0303(e)(4).
5. The DaVinci System which will be replaced will be sold or disposed of upon acquisition and installation of the replacement system. The existing system will be traded in as part of the replacement equipment purchase, and will be removed by and returned to Intuitive Surgical, Inc. The existing system will not be used again in North Carolina without proper CON authorization, if at all. See **Exhibit 1** (letter from M. Giuffrida, Intuitive Surgical, Inc.); and **Exhibit 2** (letter from Mission's Chief Operating Officer).
6. The system being replaced was new when purchased by Mission and is more than three years old. See **Exhibit 2** (letter from Mission's Chief Operating Officer).
7. The new Xi DaVinci System will have the same capabilities as the system being replaced, although it may have additional capabilities due to the advancement of technology, is functionally similar to the existing Si Robot and will be used for the same diagnostic or treatment purposes as the equipment being replaced. See **Exhibit 2** (letter from Mission's Chief Operating Officer).
8. The project will not increase patient charges or per procedure operating expenses more than 10% within 12 months of the replacement equipment being acquired. See **Exhibit 2** (letter from Mission's Chief Operating Officer).

² In calculating construction costs, our clients relied upon prior Agency determinations that the construction costs "essential to acquiring and making operational the replacement equipment" should include only those costs directly related to removing the old equipment, installing the new equipment and making sure that equipment operates properly. In the case of a CT scanner, for example, such cost should include upfit of the CT room related solely to the operation of the CT scanner (e.g., shielding, extra electrical connections), but need not include other construction costs associated with that room. Similarly, the Agency has previously determined that costs associated with the installation of equipment in the control room for the CT scanner should be included only to the extent that those costs would be different from construction related to general office space. Mission Hospitals, Inc. v. NC DHHS, ___ N.C. App. ___, 696 S.E.2d 163 (2010).

³ The Intuitive Surgical, Inc. quote received by Mission reflects charges related to multi-year service plans for the new equipment. These are operating costs, not capital costs, so we have not included them in the total project costs reflected above and on the Proposed Total Capital Cost Worksheet at **Exhibit 4**. However, even if these costs are added to the project costs, the project would still be exempt from CON review and the need to obtain a CON pursuant to the statutory exemption set forth at N.C. Gen. Stat. § 131E-184(f).

Lisa Pittman
March 26, 2021
Page 4

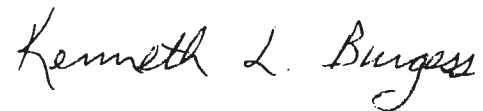
Poyner Spruill^{LLP}

Conclusion

For the reasons set forth above, we believe that the proposed replacement of Mission's existing DaVinci System is exempt from CON review and that no CON is required for the project. We respectfully request that you review the attached documentation and confirm in writing that this is the case.

Please feel free to let me know if you have questions or need additional information regarding this project.

Very truly yours,

A handwritten signature in black ink that reads "Kenneth L. Burgess". The signature is written in a cursive style with a large, prominent initial 'K'.

Kenneth L. Burgess
Partner

cc: Cathi Durham
Sondra Smith

Exhibits

EXHIBIT 1

Intuitive
1020 Kifer Road
Sunnyvale, CA 94086
T. 408 523 2100
F. 408 523 1390
intuitive.com

March 23, 2021

Mission Hospital
609 Biltmore Avenue
Asheville, North Carolina 28801

To Whom It May Concern:

This letter is to inform you that Intuitive Surgical, Inc. will be removing the existing IS3000 DaVinci robot from MH Mission Hospital and providing a trade-in credit as part of the purchase of a new DaVinci Xi Dual Console System. The IS3000 DaVinci will be returned to Intuitive Surgical, Inc. and will not be reinstalled in the state of North Carolina without the proper CON authorization.

Sincerely,

Marc Giuffrida

Signature: 
Marc Giuffrida (Mar 23, 2021 09:48 PDT)

Email: marc.giuffrida@intusurg.com

Title: Sr. Director, Contract Administration

Company: Intuitive Surgical, Inc

EXHIBIT 2



March 17th, 2021

Lisa Pittman
Assistant Chief
Healthcare Planning and Certificate of Need Section
N.C. Division of Health Service Regulation
809 Ruggles Drive
Raleigh, N.C. 27603
Via email to: Lisa.Pittman@dhhs.nc.gov

Re: MH Mission Hospital, LLLP's Notice of Exemption of Existing DaVinci Si Robot

Dear Ms. Pittman:

MH Mission Hospital ("Mission") will be replacing our existing IS3000 DaVinci Si System (the "Si Robot") with a new DaVinci Xi Dual Console system (the "Xi Robot"). The existing Si Robot is located in the Surgical Suite of the North Tower on the hospital's main campus at 509 Biltmore Avenue in Asheville, N.C. The DaVinci Si system to be replaced is currently in use. The replacement of this system 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. The DaVinci system being replaced was purchased new when acquired. The replacement Xi system will be a new unit, will have the same clinical functionality as the existing Si Robot, will be used for the same diagnostic and/or treatment purposes as the existing Si and will not be used to provide a new health service as that term is defined in the CON Laws. The new Xi Robot does possess expanded capabilities due solely to advancements in technology encompassed in the Xi Robot. The existing equipment will be traded in as part of the purchase of the new equipment and the Xi vendor is providing Mission with a trade-in on the existing Si Robot in the amount of approximately \$400,000.00.

Best Regards,

Joseph R. Rudisill
Chief Operating Officer
MH Mission Hospital, LLLP
509 Biltmore Avenue
Asheville, NC 28801
828-213-0185

EXHIBIT 3

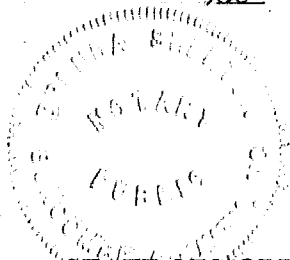
AFFIDAVIT OF JOSEPH R. RUDISILL

Joseph R. Rudisill, being first duly sworn, deposes and says as follows:

1. I am the Chief Operating Officer for MH Mission Hospital, LLLP ("Mission"), and having reached the age of majority am competent to make this Affidavit which I do on my own knowledge.
2. As part of my duties as Chief Operating Officer, I am responsible for the oversight of all operations for Mission, which includes our surgical robotics division.
3. I am personally familiar with proposed project to replace Mission's existing Intuitive DaVinci Surgical Robotic System currently located in the Surgical Suite of the North Tower on the hospital's main campus at 509 Biltmore Avenue, Asheville, N.C.
4. Under pain of perjury I certify that the total costs of the project to replace the existing IS3000 DaVinci system with a DaVinci Dual Console System will not be in excess of TWO MILLION AND 00/100 DOLLARS (\$ 2,000,000.00).
5. Furthermore, Mission will not acquire any other major medical equipment or develop any other new institutional health services described in N.C. Gen. Stat. §131E-176 (16) as part of this project.

FURTHER AFFIANT SAYETH NOT.

This the 22nd day of March, 2021.



JOSEPH R. RUDISILL
Chief Operating Officer
MH Mission Hospital, LLLP

STATE OF NORTH CAROLINA
COUNTY OF BUNCOMBE

Sworn to and subscribed before

me, this the 22nd day of March, 2021.

Notary Public

My Commission Expires: 2-12-2022

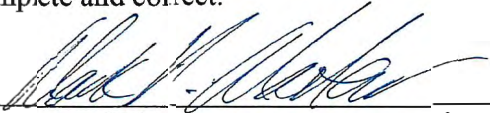
EXHIBIT 4

Projected Capital Cost Form

Building Purchase Price	NA
Purchase Price of Land	NA
Closing Costs	NA
Site Preparation	NA
Construction/Renovation Contract(s)	\$0.00
Landscaping	NA
Architect / Engineering Fees	\$0.00
Medical Equipment	\$1,845,000.00
Non-Medical Equipment	trade-in credit (\$400,000)
Furniture	NA
Consultant Fees (specify)	\$0.00
Financing Costs	\$0.00
Interest during Construction	NA
Other (specify) ancillary equipment & sales tax	\$226,829.41
Total Capital Cost	\$1,671,829.41

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.



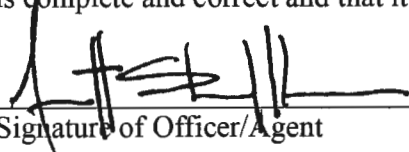
 Signature of Licensed Architect or Engineer

Date Signed: 3/23/2021



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.



 Signature of Officer/Agent

Date Signed: 03/23/2021

Garrett Shreffler Director, Facility Planning, Design & Construction
 Title of Officer/Agent

From: [Pittman, Lisa](#)
To: [Waller, Martha K](#)
Subject: FW: [External] MH Mission Hospital Exemption Notice for Replacement of DaVinci Robotics System
Date: Friday, March 26, 2021 9:56:42 AM
Attachments: [image002.png](#)
[image003.png](#)
[image004.png](#)
[Filed DaVinci Surgical System Replacement Notice of Exemption to CON Section with Exhibits.pdf](#)

Lisa Pittman

Assistant Chief

[Division of Health Service Regulation](#), Healthcare Planning and CON Section
[NC Department of Health and Human Services](#)

Help protect your family and neighbors from COVID-19.

[Know the 3 Ws. Wear. Wait. Wash.](#)

#StayStrongNC and get the latest at nc.gov/covid19.

Office: 919 855 3989

Lisa.Pittman@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704

From: Burgess, Kenneth L. <KBurgess@poynerspruill.com>
Sent: Friday, March 26, 2021 9:22 AM
To: Pittman, Lisa <lisa.pittman@dhhs.nc.gov>; Lightbourne, Ena <ena.lightbourne@dhhs.nc.gov>
Cc: Catherine.Durham@HCAHealthcare.com; sondra.Smith2@hcahealthcare.com
Subject: [External] MH Mission Hospital Exemption Notice for Replacement of DaVinci Robotics System

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

Good morning Lisa and Ena, attached please find an Exemption Notice we are filing on behalf of our client, MH Mission Hospital, LLLP, in connection with the replacement of a DaVinci Robotics System. Please let me know if you have any questions or need additional information about the attached document. Thank you, Ken Burgess

Kenneth L. Burgess | Partner

Poyner Spruill^{LLP}
ATTORNEYS AT LAW

1151 Falls Road, Suite 1000
Rocky Mount, N.C. 27804

D: 919 783 2917 | **M:** 919 449 4754

KBurgess@poynerspruill.com | www.poynerspruill.com

Due to the increasing risks posed by the spread of COVID-19, we have made the decision to have all attorneys and staff work remotely. This decision comes after much planning and close monitoring of media and local government coverage of the virus.

Maintaining a safe work environment, while continuing to serve our clients is our highest priority. We have taken steps to ensure that our attorneys and staff are equipped with the proper technology that will allow them to seamlessly serve our clients. Thank you for your patience and understanding during this time of uncertainty.



This message constitutes a confidential attorney-client communication. If you have received this communication in error, do not read it. It is not intended for transmission to, or receipt by, any unauthorized persons. Please delete it from your system without copying it, and notify the sender by reply email or by calling 919-783-6400, so that our address record can be corrected. Thank you.

Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.