



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

January 14, 2013

Catharine W. Cummer, Regulatory Counsel, Strategic Planning
Duke University Health System
3100 Tower Blvd, Box 3229
Durham NC 27707

Exempt from Review - Replacement Equipment

Facility: Duke University Health System d/b/a Duke Raleigh Hospital
Project Description: Replace existing da Vinci surgical robot
County: Wake
FID #: 923421

Dear Ms. Cummer:

In response to your letter of December 24, 2012, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the da Vinci Si Surgical Robot to replace the existing da Vinci Standard Surgical Robot [Serial # M0443804429020D]. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

It should be noted that this 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 Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Michael J. McKillip
Project Analyst

Craig R. Smith, Chief
Certificate of Need Section

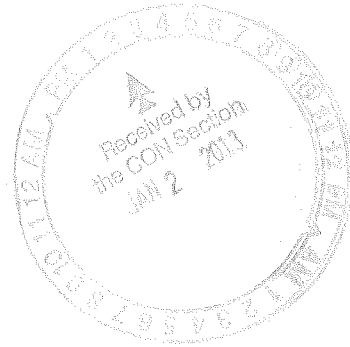
www.ncdhhs.gov • <http://www.ncdhhs.gov/dhsr>
Tel (919) 855-3873 • Fax (919) 733-8139

Location: Edgerton Building, 809 Ruggles Drive • Raleigh, NC 27603
Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704
An Equal Opportunity/ Affirmative Action Employer





Catharine W. Cummer
Regulatory Counsel, Strategic Planning



December 24, 2012

Via Electronic Mail

Michael J. McKillip, Project Analyst
Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Equipment Replacement Project at Duke Raleigh Hospital

Dear Mr. McKillip:

I am writing to notify you of the proposed acquisition of replacement surgical robotic equipment at Duke Raleigh Hospital. The equipment to be replaced is a da Vinci Standard surgical robot acquired in 2008. Both the existing and replacement equipment are surgical robots capable of providing a range of surgical procedures; the new equipment simply provides enhanced resolution, more efficient setup, and upgraded ergonomic console and settings for use in the same procedures. A completed equipment comparison form is enclosed as Exhibit 1. The manufacturer's description of the existing (Standard) and replacement (Si) systems are enclosed as Exhibit 2. Copies of the quotes for the new equipment and accessories are enclosed as Exhibit 3. The total capital cost of the project is \$823,200.

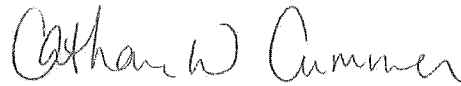
Please note that the quotes reference three pieces of equipment, which includes two replacements at Duke University Hospital which are the subject of separate correspondence in addition to the equipment to be located at Duke Raleigh Hospital. Although they are included on the same quotes because the Duke University Health System intends to implement all three replacements simultaneously, they are not dependent on each other and could be pursued separately.

The existing equipment is currently in use at Duke Raleigh Hospital, but will be removed from service in the state upon placement of the replacement equipment into service.

Mr. Mike McKillip
December 24, 2012

It is our understanding that this replacement is exempt from certificate of need review as the exempt acquisition of replacement equipment. We would appreciate your confirmation of this understanding. Thank you for your attention to this request. Should you have any questions, please let me know.

Very truly yours,



Catharine W. Cummer

Enclosures

cc: Jane Pleasants
Leigh Bleecker

EQUIPMENT COMPARISON – Duke Raleigh Hospital Surgical Robot Replacement

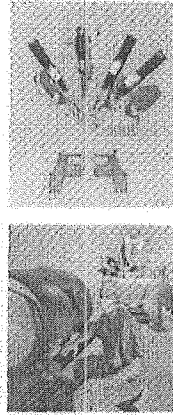
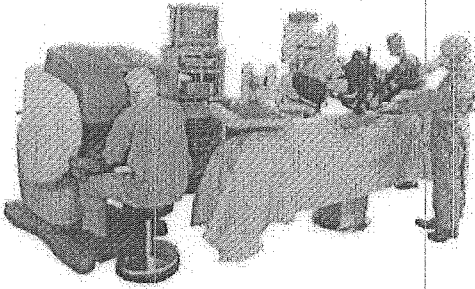
	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	da Vinci Standard Surgical Robot	da Vinci Si Surgical Robot
Manufacturer of Equipment	Intuitive Surgical	Intuitive Surgical
Tesla Rating for MRIs		
Model Number	IS2000	Si
Serial Number	MO44380429020D	N/A
Provider's Method of Identifying Equipment	Asset Tag 150606	
Specify if Mobile or Fixed	Fixed (can be used in multiple operating rooms within facility)	Fixed (can be used in multiple operating rooms within facility)
Mobile Trailer Serial Number/VIN #		
Mobile Tractor Serial Number/VIN #		
Date of Acquisition of Each Component	2008	
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>	\$737,900	\$823,200*
Total Cost of Equipment	\$725,000	\$823,200
Fair Market Value of Equipment	NA	\$823,200
Net Purchase Price of Equipment	NA	\$823,200
Locations Where Operated	Duke Raleigh Hospital	Duke Raleigh Hospital
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	NA	0
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0
Type of Procedures Currently Performed on Existing Equipment	Surgical procedures	NA
Type of Procedures New Equipment is Capable of Performing	NA	Surgical procedures

*Includes \$725,000 for robot and \$98,200 for accessories. There are no construction or installation expenses associated with this equipment.

EXHIBIT 1

Home Products da Vinci Surgical System

da Vinci Surgical System (Standard)



More Images

The first generation of the *da Vinci*[®] Surgical System, introduced in 1999, consists of an ergonomically designed surgeon's console, a patient-side cart with four interactive robotic arms, a high-performance vision system and proprietary *EndoWrist*[®] instruments. Powered by state-of-the-art robotic technology, the surgeon's hand movements are scaled, filtered and seamlessly translated into precise movements of the *EndoWrist* instruments. The net result: an intuitive interface with breakthrough surgical capabilities.

Superior Visualization

- Revolutionary 3-channel vision system
- High resolution 3-D image
- Panoramic view of the surgical field

Enhanced Dexterity, Precision & Control

- 3 robotic arms enable Solo Surgery™
- Fingertip control of *EndoWrist*[®] instruments
- 7 degrees of freedom - 90 degrees of articulation
- Motion scaling and tremor reduction

Superior Ergonomics

- Optimal alignment of visual and motor axes
- Immersive high resolution stereo viewer
- Comfortable seated posture

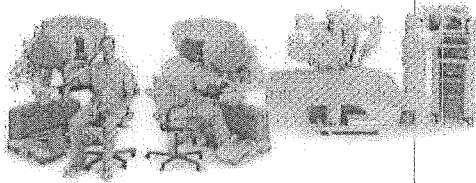
This *da Vinci* Surgical System is no longer actively commercialized in the world, but is still being supported by Intuitive Surgical through its Customer Service organization.

ShareThis

Exhibit 2

da Vinci Si^{HD} SURGICAL SYSTEM

The newly refined da Vinci Si Surgical System is the latest addition to the da Vinci[®] product line.

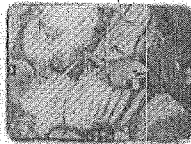


Launched in April 2009, the da Vinci Si introduces several enabling features, including:

- Dual-console capability to support training and collaboration during minimally invasive surgery.
- Enhanced high-definition 3D vision for superior clinical capability.
- An updated user interface for streamlined setup and OR turnover.
- Extensibility for digital OR integration.

Core Technology

The da Vinci Si System retains and builds on the core technology at the heart of the existing da Vinci and da Vinci S[®] Systems:

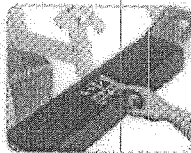


Advanced 3D HD visualization with up to 10x magnification and an immersive view of the operative field:

EndoWrist[®] instrumentation with dexterity and range of motion far greater than even the human hand.
Intuitive[®] Motion technology, which replicates the experience of open surgery by preserving natural eye-hand-instrument alignment and intuitive instrument control.

System Features & Benefits

Together, these technological advancements provide unparalleled precision, dexterity and control that enable a minimally invasive approach to many complex surgical procedures. The da Vinci Si Surgical System provides the following core benefits:



- Surgeon Control and Comfort
- Patient Safety
- OR Efficiency
- Integrated Technology & Data

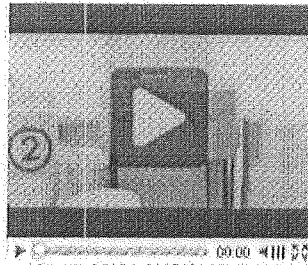
Learn More

Features and Benefits of the da Vinci Si Surgical System

To have an Intuitive Surgical representative contact you about starting a da Vinci Surgery program at your hospital, call +1 888 408 4774 or email us for more information.



Home Products da Vinci Surgical System Si



More Videos



Intuitive Surgical, Inc.
 1266 Kifer Road
 Sunnyvale, CA 94086
 877-408-dVRC (3872)

Making surgical procedures beyond the limits of the human hand

Quote Details

Quote ID	11657.0
Quote Date	12/4/2012
Valid Until	12/15/2012
Sales Rep	Michael Sayre
Phone Number	(919) 621-6731
Email	michael.sayre@intusurg.com

Company Information

Hospital Name	Duke University Medical Center
NS ID / IDN Affiliation	/
Address	2301 Erwin Road
City, State, Zip	Durham, NC, 27710
Contact Name	
Telephone	

Please Fax all Purchase Orders to: 408-523-2377

Items

Part Number	Qty	Item	Price	Discount	Subtotal
da Vinci Systems					
	3	da Vinci Si Firefly™ Fluorescence Imaging System with trade: (single console) System Surgeon Console including: One (1) Surgeon Console One (1) High Resolution Stereo Display One (1) Left Master Controller One (1) Right Master Controller One (1) Foot Switch Panel One (1) Surgeon Console to Vision Cart Cable System Patient Cart including: One (1) Patient Cart One (1) Instrument Arm One One (1) Instrument Arm Two One (1) Instrument Arm Three One (1) Camera Arm One (1) Patient Cart to Vision Cart Cable System Vision Cart System Documentation including: User's Manual For System System Software Camera Starter Kit: One (1): Firefly™ Fluorescence Camera Head with Light Guide One (1): Camera Cable Four (4): Firefly™ Fluorescence Imaging Endoscopes Two (2) 12 mm and Two (2) 8.5mm (one 30° and one 0°) One (1): 12mm Alignment Target One (1): 8.5mm Alignment Target One (1): 8.5mm Cannula Instrument and Accessory: Accessory Starter Kit: One (1): 3 Arm Drape Kit, 5 pack One (1): 4 Arm Drape Kit, 5 pack Twenty (20): Instrument Arm Drapes Twenty (20): Camera Head Drapes Twenty (20): Camera Arm Drapes Twenty (20): Monitor Drapes One (1): Spare Lamp Module (all kit subject to change without notice)	\$725,000.00	\$0.00	\$2,175,000.00
	3	Trade in of S System	\$0.00	\$0.00	\$0.00
Freight					
	3	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)	\$10,000.00	\$30,000.00	\$0.00
Total					\$2,175,000

Service

Part Number	Qty	Item	Price	Subtotal
	3	dVComplete Care Plan (Site) Years 1-5, per year	\$225,000.00	\$675,000.00

Equipment to be returned:

da Vinci System	SG122, SG472, SG434
da Vinci 0 Degree Endoscopes Quantity	11
da Vinci 30 Degree Endoscopes Quantity	9
da Vinci Camera Heads Quantity	10

Terms and Conditions

EXHIBIT 3

System Terms and Conditions

A signed Sales, License, and Service Agreement ("SLSA") or equivalent is required prior to shipment of the System (s). All site modifications and preparation are the Customer's responsibility and are to be completed to the specification given by Intuitive Surgical prior to the installation date. Freight will be invoiced separately. Subject to credit approval by Intuitive Surgical, payment terms are net 30 days from Intuitive Surgical's invoice date. Each System includes the patient side cart, vision cart, and surgeon console(s). System enhancements required to support new features may be purchased at Intuitive Surgical's then current list price. The System price of the da Vinci® Surgical System includes the initial installation of the System at Customer's facility. All taxes are the responsibility of the Customer and will be added to the invoice, as appropriate.

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

Upgrade Terms and Conditions

A signed Purchase Order and/or an addendum to the existing Sales, License, and Service Agreement ("SLSA") is required prior to shipment of the Equipment. All site modifications and preparation are the Customer's responsibility and are to be completed to the specification given by Intuitive Surgical prior to the installation date. Freight will be invoiced separately. Subject to credit approval by Intuitive Surgical, payment terms are net 30 days from Intuitive Surgical's invoice date. Additional System enhancements required to support new features may be purchased at Intuitive Surgical's then current list price. The System Upgrade price of the da Vinci® Surgical System includes the initial installation of the System at Customer's facility. All taxes are the responsibility of the Customer and will be added to the invoice, as appropriate. Subject to Availability, Terms are FOB Origin Freight PP & Add.

I&A Terms and Conditions

To place an order, please fax PO to our Order Management Department at 408-523-2377. Payment Terms Net 30 Days. Delivery via Federal Express 2 day service unless otherwise specified. Order subject to stock on hand. Pricing subject to change without notice and excludes tax and shipping costs.

Returning Goods must be authorized through the Intuitive Surgical Service Support Department. Please call 800-876-1310 to receive Return Material Authorization Number (RMA). Returns must be received within 14 days of a valid Return Authorization Number being issued or the RMA will be closed. All returns should be shipped prepaid and must be cleaned and decontaminated prior to returning to Intuitive Surgical Inc.

After failure analysis and full inspection of returned merchandise is completed, Intuitive Surgical will issue credit as a general credit to your account if original P.O. is not specified. Excess inventory returns will incur a 15% restocking fee and must be returned in original packaging unopened, unmarked, undamaged and in separate shipping container to qualify for credit. Credit will not be issued for product shipped more than 12 months prior to return request, if products is past expiration date, or if product was damage due to misuse mishandling or negligence

Warranty: Endoscopes, camera heads and sterilization trays 1 year. Instruments - lives/uses left for defective instruments, or 1 year from shipment date. Accessories Monitors and bipolar footswitch 90 days.



Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086
877-408-3872 Opt 3

Taking surgical precision beyond the limits of the human hand.

Quote Details

Quote ID	11065.0
Quote Date	11/15/2012
Valid Until	12/14/2012
Sales Rep	Michael Sayre
Phone Number	(919) 621-6731
Email	Michael.Sayre@intusurg.com
Inside Sales Rep	David Woodward 877-408-3872 Opt 3

Company Information

Hospital Name	Duke University Medical Center
NS ID / IDN Affiliation	10125/Duke University Health System
Address	2301 Erwin Rd PO Box 3708
City, State, Zip	Durham, NC, 27710-0001
Contact Name	Cynthia Blackwell
Telephone	(919) 681-9717

Please Fax all Purchase Orders to: 408-523-2377

Items

Part Number	Qty	Item	Price	Subtotal
8MM Reusable Accessory				
420260	7	8.5mm Endoscope Cannula	\$1,300.00	\$9,100.00
420319	5	8mm Flared Grounded Cannula	\$980.00	\$4,900.00
Vision System/Accessory				
370892	4	12mm Endoscope, Fluorescence, 0 Degree (Must Have Upgrade 380993)	\$18,800.00	\$75,200.00
370893	4	12mm Endoscope, Fluorescence, 30 Degree (Must Have Upgrade 380993)	\$18,800.00	\$75,200.00
372010	1	8.5 mm Fluorescence Endoscope 0°	\$21,600.00	\$21,600.00
372011	1	8.5 mm Fluorescence Endoscope 30°	\$21,600.00	\$21,600.00
371679	5	8.5mm Endoscope Alignment Target	\$500.00	\$2,500.00
381103	3	Fluorescence Camera Head (Includes Camera Cables and Light Guide Cables) Must Have 380993	\$55,000.00	\$165,000.00
Cables				
380989	4	da Vinci Si Blue Fiber Cables Kit	\$2,500.00	\$10,000.00
371715	2	Energy Activation Cables, Valleylab	\$950.00	\$1,900.00
Advanced Instruments				
_410322	3	Endowrist® One Vessel Sealer, box of 6 Subject to Availability, lead time 3-14 weeks	\$3,570.00	\$10,710.00
Seals				
420206	2	8.5mm Cannula Seals (8.5-13mm seal)	\$400.00	\$800.00
Total				\$398,510

Terms and Conditions

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