



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

Pat McCrory  
Governor

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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 University Hospital  
Project Description: Replace two existing da Vinci surgical robots  
County: Durham  
FID #: 943138

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 two da Vinci Standard Surgical Robots to replace the two existing da Vinci Standard Surgical Robots [Serial # SG122 and SG472]. This determination is based on your representations that the existing units 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 numbers 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 P. Smith, Chief  
Certificate of Need Section

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

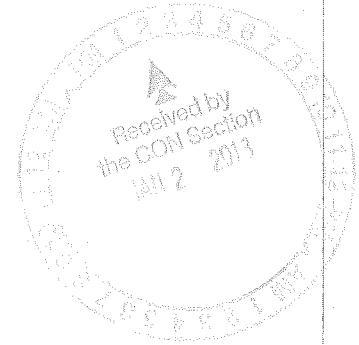
Location: Edgerton Building, 809 Ruggles Drive • Raleigh, NC 27603  
Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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 University Hospital

Dear Mr. McKillip:

I am writing to notify you of the proposed acquisition of two units of replacement surgical robotic equipment at Duke University Hospital. Both pieces of equipment to be replaced are da Vinci Standard surgical robots acquired in 2006 and 2008 respectively. 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.

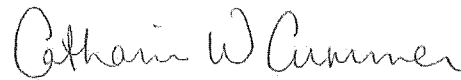
Please note that the quotes reflect the acquisition three pieces of equipment, the two replacements at Duke University Hospital and a third replacement for equipment located at Duke Raleigh Hospital. Although they are included on the same quotes because Duke intends to implement all three replacements simultaneously, they are not dependent on each other and could be pursued separately.

The existing equipment is currently in use at Duke University 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 these replacements are exempt from certificate of need review as exempt acquisitions 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  
Rebecca McKenzie

EQUIPMENT COMPARISON - Duke University Hospital Surgical Robot Replacement

	EXISTING EQUIPMENT (1)	EXISTING EQUIPMENT (2)	REPLACEMENT EQUIPMENT (1)	REPLACEMENT EQUIPMENT (2)
Type of Equipment (List Each Component)	daVinci Standard Surgical Robot	daVinci Standard Surgical Robot	daVinci Standard Surgical Robot	daVinci Standard Surgical Robot
Manufacturer of Equipment	Intuitive Surgical	Intuitive Surgical	Intuitive Surgical	Intuitive Surgical
Tesla Rating for MRIs	N/A	N/A	N/A	N/A
Model Number	DiVinci S	DiVinci S-HD	DiVinci SI with Dual Console	DiVinci SI with Dual Console
Serial Number	SG122	SG472	N/A	N/A
Provider's Method of Identifying Equipment	Asset tag 146662	Asset tag 150999		
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)	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 #	N/A	N/A	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A	N/A	N/A
Date of Acquisition of Each Component	2006	2008	2012	2012
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	Used	Used	New	New
Total Capital Cost of Project (including Construction, etc.)	\$725,000	\$735,000	\$1,375,155*	\$1,375,155*
Total Cost of Equipment	\$725,000	\$735,000	\$1,375,155	\$1,375,155
Fair Market Value of Equipment			\$1,375,155	\$1,375,155
Net Purchase Price of Equipment	\$725,000	\$735,000	\$1,375,155	\$1,375,155
Locations Where Operated	Duke University Hospital	Duke University Hospital	Duke University Hospital	Duke University Hospital
Number Days In Use/To be Used in N.C. Per Year	365	365	365	365
Percent of Change in Patient Charges (by Procedure)	NA	NA	0	0
Percent of Change in Per Procedure	NA	NA	0	0

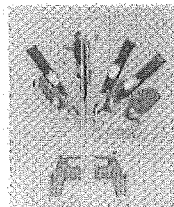
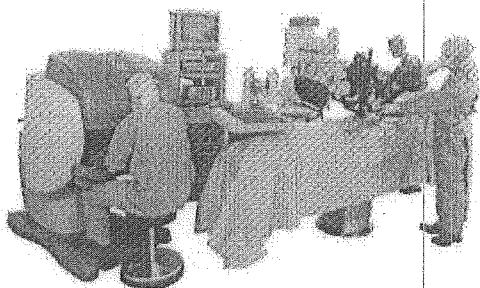
EXHIBIT 1

Operating Expenses (by Procedure)					
Type of Procedures Currently Performed on Existing Equipment	Surgical procedures	Surgical procedures	Surgical procedures	Surgical procedures	
Type of Procedures New Equipment is Capable of Performing	NA	NA	NA	NA	

\*The negotiated total price from the vendor, who is unaffiliated with Duke University Health System, reflects the fair market value of the equipment. This includes \$725,000 for the robot, \$500,000 for the console and features included in the console package price, and \$150,155 for accessories associated with each replacement. There are no construction or installation expenses associated with this equipment.

Home Products da Vinci Surgical System

### da Vinci Surgical System (Standard)



The first generation of the *da Vinci*<sup>®</sup> Surgical System, introduced in 1999, consists of an ergonomically designed surgeon's console, a patient-safe cart with four interactive robotic arms, a high-performance vision system and proprietary *EndoWrist*<sup>®</sup> 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.

More Images

#### 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*<sup>™</sup>
- Fingertip control of *EndoWrist*<sup>®</sup> 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

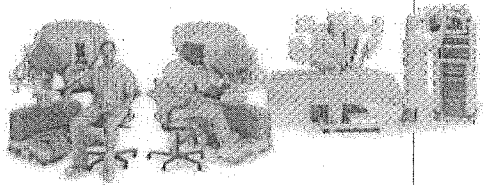
This *da Vinci* Surgical System is no longer actively commercialized in the world, but is still being supported by Intuitive Surgical through its Customer Service organization.

ShareThis

Exhibit 2

# da Vinci Si Si 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

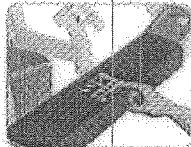
The *da Vinci Si* System retains and builds on the core technology at the heart of the existing *da Vinci* and *da Vinci S* Systems:



- Advanced 3D HD visualization with up to 10x magnification and an immersive view of the operative field.
- EndoWrist<sup>®</sup> instrumentation with dexterity and range of motion far greater than even the human hand.
- Intuitive<sup>®</sup> 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

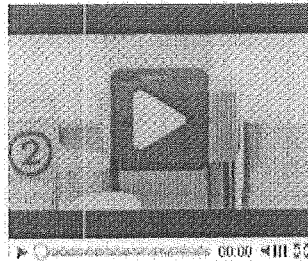
## Learn More

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 +1 888 409 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 practice beyond the limits of the human hand™*

**Quote Details**

**Company Information**

Quote ID	11657.0	Hospital Name	Duke University Medical Center
Quote Date	12/4/2012	NS ID / IDN Affiliation	/
Valid Until	12/15/2012	Address	2301 Erwin Road
Sales Rep	Michael Sayre	City, State, Zip	Durham, NC, 27710
Phone Number	(919) 621-6731	Contact Name	
Email	michael.sayre@intusurg.com	Telephone	

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

**Items**

Part Number	Qty	Item	Price	Discount	Subtotal
<b>da Vinci Systems</b>					
	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
<b>Freight</b>					
	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
<b>Total</b>					<b>\$2,175,000</b>

**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**

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**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®

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

*Always request quotes beyond the limits of our online tools!*

## Quote Details

Quote ID	11654.0
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
<b>da Vinci System Upgrades</b>					
	3	da Vinci Skills Simulator Equipment List: One (1) Skills Simulator Unit One (1) Blue Fiber Cable One (1) Audio Cable Warranty 1 Year from Acceptance Date	\$85,000.00	\$255,000.00	\$0.00
	2	Dual Console/Additional Surgeon's Console da Vinci Dual Console - Additional SI Surgeon Console for proctoring and surgical assist - includes Video Expansion Kit (2 TilePro Inputs and 2 video outputs at vision cart for integrated OR installations, and 3D display) Customer acknowledges that the da Vinci Dual Surgeons Console comes with a one (1) year warranty period. Thereafter, the Annual Service Fee for the da Vinci®™ Surgical System(s) will increase by \$25,000. The pricing may be prorated in the second year to be co-terminus with the System Service pricing. THE AFOREMENTIONED CUSTOMER ACKNOWLEDGEMENT PROVISIONS MUST BE CONTAINED IN YOUR PURCHASE ORDER	\$500,000.00	\$0.00	\$1,000,000.00
	3	FireFly™ Fluorescence Imaging Upgrade 12mm Endoscopes Hardware upgrade kit to enable intra-operative image guidance using indocyanine green fluorescing dye Upgrade Kit includes: da Vinci® FireFly Illuminator da Vinci® FireFly 12mm 0° Endoscope da Vinci® FireFly 12mm 30° Endoscope da Vinci® FireFly HD Camera head and cable Hardware Upgrade Kit Please Note: Existing Illuminator is removed from the Customer site to be replaced with new Fluorescence Imaging capable components. Cameras and endoscopes remain on site, and are backwards compatible with upgrade	\$100,000.00	\$300,000.00	\$0.00
	3	Single-Site™ Base Starter Kit Single-Site™ Starter Kit Training Kit	\$44,015.00	\$132,045.00	\$0.00
	3	Vessel Sealer and Stapler Vision Cart Upgrade 381125 VIO 300D 381124 Instrument Control Box (if required) Subject to Availability, 45-60 day lead time	\$16,500.00	\$49,500.00	\$0.00
<b>Total</b>					<b>\$1,000,000</b>

## Additional Information

If the Fluorescence Imaging Upgrades are purchased at the time of the System purchases, each upgrade will also include a set of 8.5mm Fluorescence Scopes (0 & 30).

## Terms and Conditions

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#### I&A Terms and Conditions

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

*Taking surgical systems 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
<b>8MM Reusable Accessory</b>				
420260	7	8.5mm Endoscope Cannula	\$1,300.00	\$9,100.00
420319	5	8mm Flared Grounded Cannula	\$980.00	\$4,900.00
<b>Vision System/Accessory</b>				
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
<b>Cables</b>				
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
<b>Advanced Instruments</b>				
410322	3	Endowrist® One Vessel Sealer, box of 6  Subject to Availability, lead time 3-14 weeks	\$3,570.00	\$10,710.00
<b>Seals</b>				
420206	2	8.5mm Cannula Seals (8.5-13mm seal)	\$400.00	\$800.00
<b>Total</b>				<b>\$398,510</b>

**Terms and Conditions**

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