

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section

2704 Mail Service Center • Raleigh, North Carolina 27699-2704
<http://www.ncdhhs.gov/dhsr/>

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor
Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief
Phone: (919) 855-3873
Fax: (919) 733-8139

July 6, 2012

Ms. Barbara L. Freedy
Director, Certificate of Need
Novant Health, Inc.
2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

RE: Exempt from Review – Replacement Equipment / Forsyth Memorial Hospital d/b/a Forsyth Medical Center / Replacement of Da Vinci Surgical System in Women's Center operating room / Forsyth County
FID# 923174

Dear Ms. Freedy:

In response to your letter of June 12, 2012, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a) (7). Therefore, Forsyth Medical Center (FMC) may proceed to acquire, without a certificate of need, an Intuitive Surgical Da Vinci Si Surgical System to replace the existing Da Vinci Surgical System, serial number S00381, located in FMC Women's Center, operating room. This determination is based on your representations that the existing unit will be removed as soon as possible 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.

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,

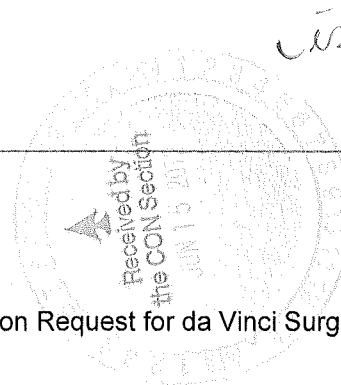
Lisa Pittman, Team Leader

Craig Smith, Chief
Certificate of Need Section



Freedy, Barbara

From: Freedy, Barbara
Sent: Tuesday, June 12, 2012 5:58 PM
To: 'lisa.pittman@dhhs.nc.gov'; 'Frisone, Martha'
Subject: Forsyth Medical Center CON Replacement Equipment Exemption Request for da Vinci Surgical System in Women's Center Surgical Suite
Importance: High
Attachments: 20120612174330886.pdf



Lisa and Martha: attached is a CON replacement equipment exemption request for a new da Vinci Surgical (robotic) System for the Forsyth Medical Center Women's Center surgical suite. FMC is located at 3333 Silas Creek Parkway, Winston-Salem, NC 27103 (Forsyth County). Pursuant to NCGS Section 131E-184(a)(7), the letter and its attachments serve as notification of intent to proceed with this project. We would appreciate your written confirmation that this project is exempt from CON review.

I will also send you a copy of this exemption request by U.S. Mail to the CON Section offices in Raleigh.

Please do not hesitate to contact me if you have questions. Thank you for your time and consideration of this matter.

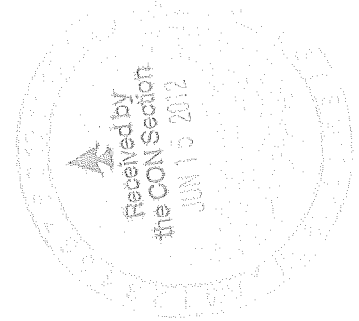
Barbara Freedy

Novant Health, Inc.
Director, Certificate of Need
2085 Frontis Plaza Blvd.
Winston-Salem, NC 270103
Ph: 336-718-4483 Cell: 336-314-9250
PC Fax: 336-277-0526

06/12/2012



Remarkable People. Remarkable Medicine.



June 12, 2012

Lisa Pittman, Team Leader
Certificate of Need (CON) Section
NC Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

RE: Replacement Equipment Exemption Request –Da Vinci Surgical System at Novant Health’s Forsyth Medical Center (FMC) Women’s Center Operating Rooms-- Forsyth County

Dear Ms. Wilson:

This letter outlines Forsyth Medical Center’s request to replace an existing Intuitive Surgical Da Vinci Surgical System with a new Intuitive Surgical Da Vinci Surgical System. The estimated total cost to acquire and implement the project is \$725,000, including the da Vinci “Si” Surgical System, and the component parts listed on page 2 of Attachment A. There is no construction or design costs associated with this as the da Vinci is a mobile system. Please see the vendor’s (Intuitive Surgical’s) equipment quote included as Attachment A, the Sales Agreement between Forsyth Memorial Hospital d/b/a Forsyth Medical Center and Intuitive Surgical, Inc. (Attachment B) and a summary of the Total Capital Costs in Attachment C. This project cost does not include sales, property, or excise taxes as FMC is a non-profit, tax-exempt organization and is not subject to these taxes. Furthermore, Intuitive Surgical will be the vendor removing the existing FMC da Vinci System from the FMC Women’s Center OR. Both the cost of the removal the existing FMC da Vinci unit and the cost of the delivery to FMC of the new da Vinci “Si” Surgical System are included in Intuitive Surgical’s \$725,000 price quote. See page 12 of Attachment B. Please see a letter from the vendor, Intuitive Surgical, regarding the removal of the FMC Women’s Center existing da Vinci Surgical System, which is included as Attachment D.

Both the existing equipment and the replacement equipment are comparable medical equipment as explained in the following pages. This project should be approved by the Agency as exempt pursuant to N.C.G.S. Section 131E-184(a)(7).

This exempt project will replace a functionally similar equipment item. The existing da Vinci Surgical System is used for surgical cases at the FMC Women’s Center and the proposed new da Vinci Surgical System is consistent with the replacement equipment definition at 10 NCAC 03R.0214(d) which states that the replacement equipment is comparable to the equipment being replaced if it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements.

Pursuant to 10A NCAC 14C.0303, the proposed da Vinci Surgical System equipment constitutes replacement equipment because:

1. It is comparable to the equipment currently in use. It has the same technology as the equipment currently in use, although it does possess expanded capabilities due to technological improvements.
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.
3. The acquisition of the new equipment will not result in more than a 10 percent increase in patient charge or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.
4. The existing equipment was not purchased second-hand nor was the existing equipment leased (as a non-capital lease).
5. The replacement equipment is not capable of performing procedures that will result in the provision of a new health service or type of procedure that has not been provided with the existing equipment.

Attached for your convenience please find:

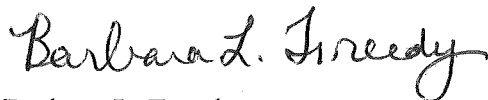
- A. a vendor equipment price quote (Attachment A);
- B. the Sales Agreement between Forsyth Medical Center and Intuitive Surgical, Inc. (Attachment B)
- C. the project/capital cost worksheet which identifies the components of the project costs (Attachment C);
- D. the NC CON equipment comparison form summarizing essential information about the proposed equipment purchase (Attachment D);
- E. letter from the equipment vendor regarding the removal of the existing FMC Women's Center da Vinci Surgical System (Attachment E); and,

As discussed above, the total cost for the project is \$725,000. This is below the \$2 Million statutory exemption threshold for replacement equipment. The equipment is being purchased for the sole purpose of replacing the existing equipment.

In conclusion, based on the information described above, please confirm that FMC's replacement equipment request does not constitute a "new institutional health service" set forth in N.C. GS Section 131E-176(16) and that it does fit within the replacement equipment exemption definition. Therefore, it is not subject to certificate of need review.

Please let us know as soon as possible if you need additional information to assist in your consideration of this request. Thanks you for your prompt consideration of this request.

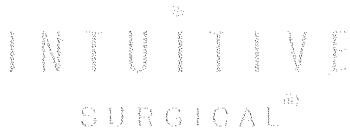
Sincerely,



Barbara L. Freedy
Director, Certificate of Need
Novant Health, Inc.

Enclosures

CC: Martha Frisone, Assistant Chief, CON Section
Teresa Carter, VP & COO, MPH & FMC Surgical Services
Marty Haynes, Novant, Strategic Sourcing



Quote Date: June 12, 2012 Quote Expiration Date: June 30, 2012 Quote Number: IS6122012JP8

Customer Name/Address:

Forsyth Memorial Hospital
 3333 Silas Creek Parkway
 Winston-Salem, NC 27103

Contact Intuitive Surgical for more information:

Contact Name: Todd Headrick
 Title: Area Sales Manager
 Phone: 843-991-4849
 E-mail: todd.headrick@intusurg.com
 Customer Service Fax Number: (408) 523-2377

Intuitive Surgical is pleased to provide you with the following Quote:

System Type: **da Vinci Surgical System: Si (single console)**

Please see attached for the description of the System Components and Instruments / Accessories provided for the System fees.

System Fee/ea:	\$725,000
Quantity:	1

System Total: \$725,000

Included in the system price:

2 da Vinci Trainings
 System Installation and Freight

Additionally: 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. If quote contains Skills Simulator, Vessel Sealer Generator Kit or Single Site Starter Kit, shipping is subject to availability terms are FOB Origin, freight PP & Add

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.

da Vinci® Si™ Surgical System (with single console) Equipment List

Intuitive will provide Customer with the following:

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
- Warranty period: One (1) year from the Acceptance date.

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
- Warranty period: One (1) year from the Acceptance date.

System Vision Cart

- Warranty period: One (1) year from the Acceptance date.

System Documentation including:

- User's Manual For System
- Warranty period: Not Applicable.

System Software

- Warranty period: One (1) year from the Acceptance date.

Instrument and Accessory:

Accessory Starter Kit (Starter Kit contents subject to change without notice)

- 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): Box of 10: 8mm Cannula Seals
- One (1): Box of 3: 8mm Cannula
- One (1): Cannula Gage Pin
- One (1): Blunt Obturator
- One (1) Box of 24: Bladeless Obturator
- One (1): Blade Protector
- One (1): Allen Wrench
- One (1): Spare Lamp Module
- Warranty period: Ninety (90) days from the Acceptance date

Instrument and Accessory:

Camera Starter Kit: (Starter Kit contents subject to change without notice)

- One (1): 3D-HD Camera Head with Light Guide
- One (1): Camera Cable
- One (1): 0 degree Endoscope
- One (1): 30 degree Endoscope
- One (1): Alignment Target
- Warranty period: One (1) year from the Acceptance date.

Instrument and Accessory:

Training Instrument Starter Kit (Starter Kit contents subject to change without notice)

- One (1): Large Needle Driver
- One (1): ProGrasp™ Forceps
- One (1): Maryland Bipolar Forceps
- One (1): Curved Scissors
- One (1): Tenaculum Forceps
- One (1): Suture Cut Needle Driver
- Warranty period: One (1) year from the Acceptance date.

(equipment list rev 08/2011)

da Vinci Skills Simulator Equipment List:

- One (1) Skills Simulator Unit
- One (1) Blue Fiber Cable
- One (1) Audio Cable

SALES AGREEMENT

Agreement No.: 06JUN12-FOR-SALES

THIS SALES AGREEMENT ("Agreement") dated as of June 11, 2012 (the "Effective Date") is made by and between INTUITIVE SURGICAL, INC., a Delaware corporation ("Intuitive"), located at 1266 Kifer Road, Sunnyvale, California 94086 and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center located at 3333 Silas Creek Parkway, Winston-Salem, NC 27103 ("Purchaser").

1. INTRODUCTION

Purchaser agrees to purchase or license from Intuitive, and Intuitive agrees to sell or license to Purchaser, certain equipment and software comprising Intuitive's *da Vinci*® S⁷™ Surgical System according to the terms and conditions of this Agreement.

2. SYSTEM

2.1 Definitions. "System" means the equipment and software comprising the *da Vinci*® Surgical System set forth on the list attached as Exhibit A consisting of certain hardware components, (the "Hardware"), software program elements (the "Software") and related documentation (the "Documentation"), that Purchaser may purchase, license or otherwise obtain under this Agreement. "Accessories" shall mean the reusable and disposable accessories set forth in Exhibit A, for use with the System that Purchaser may purchase, license or otherwise obtain under this Agreement.

2.2 Intuitive's Obligations

(a) **Delivery Date.** Intuitive will use reasonable efforts to deliver the System on or before **June 25, 2012** (the "Delivery Date"), provided that Intuitive shall not be obligated to deliver the System, prior to the date that Intuitive's designated personnel are available to attend such delivery. Each party will provide the other party with thirty (30) days' advance notice of any change in the Delivery Date. Purchaser shall fully cooperate with Intuitive to permit Intuitive to install the System. The System shall be deemed accepted by Purchaser upon delivery to Purchaser's designated location. Purchaser shall also provide Intuitive with information, consultation and advice reasonably necessary to permit such installation. If the System is not fully operational in accordance with its specifications and as required under this Agreement within thirty (30) days following the date of delivery, then Customer shall have the right to return the System to Intuitive and receive a replacement System at no cost.

(b) **Delivery Terms.** Intuitive will deliver the System to Purchaser's designated location using a carrier selected by Intuitive and at Intuitive's expense. Title and risk of loss or damage shall pass to Purchaser upon delivery of the System at Purchaser's facility.

(c) **On-Site Support.** Intuitive agrees to provide standard on-site support to designated personnel and at Purchaser's facility, on the proper operation and upkeep of the System in order for Purchaser to operate the System and as further described in Section 2.3. To clarify, this support includes, but is not necessarily limited to, training on draping the System for use in surgery, proper attachment of Instruments and Accessories, and cleaning of parts of the System and the Instruments and Accessories. The cleaning to be performed regularly by Purchaser is described in the Documentation.

2.3 Purchaser's Obligations

(a) **Use of System.** Purchaser shall ensure the proper use, management and supervision of the System. Purchaser will use the System only with surgical instruments and accessories made or approved by Intuitive, and shall not, nor shall Purchaser permit any third party to, modify, disassemble, reverse engineer, alter or misuse the System and/or the Accessories. Such actions shall include, but shall not be limited to (i) adding to, or subtracting from the System, any Purchaser or third party equipment, hardware, firmware or software, or (ii) reconfiguring any of the Intuitive equipment, hardware, firmware or software as originally provided to Purchaser as part of the System, without the express written permission from Intuitive. In addition, Purchaser shall be liable for any and all damages, whether foreseeable, consequential or incidental, incurred by Intuitive and arising or resulting, directly or indirectly, from Purchaser's breach of the above prohibition against modification, disassembly, reverse engineering, alteration or misuse of the System, instruments or accessories. Purchaser shall ensure that the System is moved and/or operated only by trained personnel in accordance with the Documentation and Intuitive's instructions. In the event Purchaser fails to comply with the requirements of this Section 2.3, Intuitive may terminate this Agreement and any warranties applicable to the System shall become void. Purchaser agrees that Intuitive will not be liable for, any claims, including any third party claims or damages caused by Purchaser's failure to comply with the requirements of this Section 2.3.

(b) **Unauthorized Instruments and Accessories.** Purchaser acknowledges that the System is designed for use only with surgical instruments and Accessories made or approved by Intuitive. In the event Purchaser uses the System with any surgical instrument or Accessory that is not made or approved by Intuitive, Intuitive may terminate this Agreement and any warranties applicable to the System shall become void.

2.4 Price and Payment Terms for the System

(a) **Price.** Purchaser shall issue a purchase order for and shall pay to Intuitive the price set forth in **Exhibit A** for the System and Accessories purchased under this Agreement according to the payment terms set forth in **Exhibit A** below. The price set forth in **Exhibit A** does not include any additional charges for taxes and similar costs, to the extent applicable, which shall be invoiced separately by Intuitive.

(b) **Payment Terms.** Upon Acceptance, Intuitive will submit to Purchaser an invoice for amounts due under this Agreement and Purchaser shall pay such invoiced amount within thirty (30) days after the date of invoice and Acceptance of the System described in Section 2.2 (a). Interest will accrue from the date on which payment is due at a rate of twelve percent (12%) per annum or the maximum rate permitted by applicable law, whichever is lower.

(c) **Funding Entity.** A funding entity ("Funding Entity") may provide the funding for Purchaser to purchase the System defined herein, provided however, Purchaser remains responsible for payment in full according to the terms of this Agreement if Funding Entity fails to pay. A Funding Entity will have no rights or obligations whatsoever under this Agreement, except as specified in this Agreement. Purchaser acknowledges and agrees that once Acceptance has occurred and title of the System has passed to the Purchaser, if Purchaser subsequently enters into an arrangement with a Funding Entity, then Purchaser will enter into an agreement (such as a sale and lease-back agreement) directly with the Funding Entity that does not involve Intuitive. Intuitive will not reverse the sale of the System to Purchaser in order to sell it to another entity, including but not limited to a Funding Entity

(d) **Security Interest.** Intuitive will retain a security interest in the System and Accessories until payment of the full purchase price has been remitted to Intuitive. Purchaser agrees to perform all acts Intuitive reasonably deems necessary or appropriate to perfect and maintain such security interest. In the event of default by Purchaser of its payment obligations for the purchase of the System set forth hereunder, Intuitive shall have the right, without liability to Purchaser after written notice of default and reclamation to Purchaser and 10 (ten) business days to cure, to reclaim the System and Accessories sold hereunder, in which case Purchaser shall be relieved of any further obligations to pay hereunder.

2.5 Software Licenses and Restrictions

(a) **Software License.** Software embedded within the System is provided under license and is not sold to Purchaser. Subject to the terms and conditions of this Agreement, Intuitive grants to Purchaser a non-exclusive, non-transferable, fully paid, restricted use license to use the Software solely as incorporated in the System in machine-executable object code form and solely in connection with the operation of the System as described in the Documentation. Purchaser shall not use, copy, modify or transfer the Software or any copy thereof, in whole or in part, except as expressly provided in this Agreement. In addition, Purchaser shall not reverse engineer, decompile, disassemble, attempt to derive the Source Code for, or otherwise manipulate the Software. Notwithstanding the foregoing, manipulation of the Software is permitted if, and then only to the extent that, the foregoing prohibition on manipulation is required to be modified by applicable law; provided, however, that Purchaser must first request from Intuitive the information to be sought from the Software, and Intuitive may, in its discretion, provide such information to Purchaser under good faith restrictions, and/or impose reasonable conditions on such use of the Software. Purchaser acknowledges and agrees that the structure and organization of the Software are valuable trade secrets of Intuitive and Purchaser agrees to protect the Software as Intuitive's Proprietary Information. Intuitive reserves all rights to the Software not expressly granted to Purchaser herein. The Software shall be deemed to be part of the "System" and shall be subject to all of the terms and conditions applicable to the System set forth hereunder.

(b) **Instruments and Accessories.** Purchaser acknowledges and agrees that all Intuitive surgical instruments Purchaser obtains from Intuitive are pursuant to a limited license to use those instruments with, and prepare those instruments for use with, the System. This license expires with the expiration of the instruments' useful lifetimes as set forth in the documentation accompanying such instruments. Any other use of Intuitive's instruments, whether before or after instrument expiration, including repair, refurbishment or reconditioning, is prohibited.

(c) **Software Warranty.** The Software (and any portions or components thereof) does not and shall not in the future contain any virus, timer, clock, counter or other limiting design or routine that causes or could cause the Software (or any portion thereof) to become erased, inoperable, impaired, or otherwise incapable of being used in the full manner for which it was designed and licensed. In the event of a nonconformity with this representation and warranty, Intuitive shall, at Intuitive sole expense, promptly modify, correct, or enhance the noncompliant Software necessary to render such Software in compliance with this representation and warranty.

2.6 System Warranty and Disclaimers

(a) **System Warranty.** Intuitive warrants to Purchaser that the System as delivered will be free and clear of all liens and encumbrances (except as otherwise set forth in this Agreement) and for the period specified in Exhibit A will be free from defects in material and workmanship, will

meet the general purposes for which it is to be used, and will conform in all material respects to the Documentation in normal use. Intuitive's obligations under this warranty are limited to the repair, or at Intuitive's option, replacement of all or part of the System provided however, that if a component is repaired three times in thirty (30) days and such component is still not repaired, Intuitive shall replace such component of the System or replace the System at Purchaser's option. All replacement parts or System shall be warranted for the remaining warranty period of the replaced part or System. This warranty is void with respect to any claims arising from (i) any repair, modification, disassembly, alteration, reconfiguration, or misuse of the System by Purchaser or any third party without the express written permission of Intuitive; (ii) the System, to the extent Purchaser has not operated or maintained the System in accordance with any reasonable handling or operating instructions supplied by Intuitive, or to the extent Purchaser has used the System with surgical instruments or accessories that are not made or approved by Intuitive; or (iii) the System to the extent that Purchaser or Purchaser's employee, agent, or contractor has subjected it to unusual physical or electric stress, misuse, abuse, negligence or accident. The foregoing expresses Purchaser's sole remedy, and Intuitive's sole liability, for any breach of warranty with respect to the System by Intuitive hereunder.

(b) No Other Warranties. INTUITIVE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, IN CONNECTION WITH THE SALE OF THE SYSTEM OR ADDITIONAL EQUIPMENT, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY TITLE AND NON-INFRINGEMENT. SOME JURISDICTIONS DO NOT ALLOW THE LIMITATION OR EXCLUSION OF IMPLIED WARRANTIES, IN WHICH EVENT THE ABOVE LIMITATION SHALL APPLY ONLY TO THE EXTENT PERMITTED BY LAW.

3. TERMINATION AND SURVIVAL.

Either party shall have the right to terminate this Agreement if the other party breaches a material term or condition of this Agreement and fails to cure such breach following thirty (30) days' written notice. Sections 2.3, 4, 5, 6, and 8 will remain in effect notwithstanding the expiration or termination of this Agreement. Section 2.4(b) shall remain in effect notwithstanding the expiration or termination of this Agreement unless Purchaser terminates this Agreement for Intuitive's breach. Section 2.5 shall remain in effect notwithstanding the expiration or termination of this Agreement unless Intuitive terminates this Agreement for Purchaser's breach.

4. INDEMNIFICATION.

4.1 By Intuitive. To the extent allowable by law, Intuitive hereby assumes all liability for, and agrees to indemnify, defend and hold harmless Purchaser and its successors, permitted assigns, medical staff, agents and employees from and against, any and all liabilities, losses, damages, claims and expenses to the extent that they arise from third party claims, actions or demands including without limitation, claims by third parties arising in contract or tort (including negligence), strict liability or otherwise (collectively, "Claims") in any way relating to or arising from (a) Intuitive's, or its employees', agents', contractors', affiliates' or representatives', breach of any of Intuitive's representations or warranties or any other obligation hereunder, or (b) Intuitive's negligence or willful misconduct; provided that Intuitive's indemnification obligations under this Section 4.1 shall not apply to the extent that such Claims arise from Purchaser's negligence or willful misconduct or breach of any of its material obligations hereunder.

4.2 By Purchaser. To the extent allowable by law, Purchaser hereby assumes all liability for, and agrees to indemnify, defend and hold harmless Intuitive and its successors, permitted assigns, agents and employees from and against, any and all Claims by third parties to the extent that they arise from: (a) Purchaser's or its employees', medical staff's, agents', affiliates' or representatives' negligence or willful misconduct in the use, possession, or operation of the System or (b) Purchaser's breach of any of its representations or warranties or any other material obligation hereunder, including without limitation Purchaser's failure to comply with the requirements of Section 2.3(b). Notwithstanding the foregoing, Purchaser's indemnification obligations under this Section 4.2 shall not apply to the extent that such Claims arise from Intuitive's or its employees', agents', contractors', affiliates', or representatives' negligence or willful misconduct or breach of any of its material obligations hereunder.

4.3 Intellectual Property Indemnification. Intuitive agrees to indemnify defend, and hold Purchaser harmless against all liabilities, expense, loss, or damage in connection with any third party claim that the System infringes any third party patent, trade secret, or copyright, provided that (i) Purchaser shall promptly notify Intuitive that such a claim has been made, (ii) Purchaser shall provide all reasonable cooperation assisting Intuitive in the defense or settlement of such claim; and (iii) Intuitive shall control the defense or settlement of any such claim at its cost and with its choice of counsel. If Purchaser is enjoined from the use of the System due to any such claim, Intuitive shall promptly, at its option and expense, either (i) substitute the System or any part thereof with non-infringing material which will perform substantially in accordance with the Documentation; (ii) obtain the right of Purchaser to continue to use the System; or (iii) remove the System and refund to Purchaser the purchase price of the System, less reasonable depreciation.

Despite the provisions of this Section 4.3, Intuitive has no obligation to the extent any claim of infringement that is based upon or arises out of: (i) any modification to the System or Software if the modification was not made by or for Intuitive; or (ii) the use or combination of the System or Software with any hardware, software, products, data or other materials not specified, provided or approved by Intuitive

THE PROVISIONS OF THIS SECTION 4.3 STATE THE SOLE AND EXCLUSIVE OBLIGATIONS OF INTUITIVE FOR ANY PATENT, COPYRIGHT, TRADEMARK, TRADE SECRET OR OTHER INTELLECTUAL PROPERTY RIGHTS INFRINGEMENT.

4.4 Claim Notification Requirement. A party seeking indemnification under this Section 4 shall promptly notify the indemnifying party of the claim after becoming aware of it. The indemnifying party shall have no indemnity obligation to the extent that unreasonable delay in notification prejudices the indemnifying party. The indemnifying party shall have the right to control the defense or settlement of any such claim at its cost and with its choice of counsel. The indemnified party shall provide all reasonable cooperation to assist the indemnifying party in the defense or settlement of such claim.

5. LIMITATION OF LIABILITY

Except for a breach of the obligations set forth in Sections 2.3(a), 2.5, 6, 8.15 and 8.17, and the indemnity obligations of Section 4, and to the extent permitted by applicable law: (i) each party's aggregate liability to the other for claims relating to this Agreement, whether for breach in contract or tort (including negligence), shall be limited to the amounts paid or owed by Purchaser under this Agreement; (ii) neither party shall be liable for any indirect, punitive, special, incidental or consequential damages in connection with or arising out of this Agreement (including loss of business,

revenue, profits, use, data or other economic advantage), even if that party has been advised of the possibility of such damage; and (iii) any liability for damages shall be limited and excluded, even if any exclusive remedy provided for in this Agreement fails of its essential purpose. Some jurisdictions do not allow the limitation of liability for incidental or consequential damages; in such jurisdictions the foregoing limitation of liability shall apply only to the extent permitted by law.

6. PROPRIETARY INFORMATION

Each party ("Receiving Party") agrees to hold all Proprietary Information of the other party ("Disclosing Party") in strict confidence and shall not use for any purpose, or disclose to any third party, any such Proprietary Information, except (i) as expressly authorized in this Agreement or in writing by the Disclosing Party, and (ii) solely to benefit the Disclosing Party and/or further the relationship of the parties. The Receiving Party shall use the same degree of care to protect the Proprietary Information as Receiving Party uses to protect its own information of like kind, which in any event shall include all reasonable steps to maintain the confidentiality of such information. For purposes of this Agreement, Proprietary Information shall include but not be limited to (1) all non-public information obtained by the Receiving Party from the Disclosing Party which (a) relates to the Disclosing Party's past, present or future research, development or business activities or the results of such activities; or (b) the Disclosing Party has received from others and is obligated to treat as confidential and proprietary; and (2) all information derivable from the System or the Accessories, but excluding information that can be learned simply through observation of the System and its operation. Proprietary Information shall not include information previously known by the Receiving Party as demonstrated by Receiving Party's contemporaneous written records, nor information publicly disclosed without breach of an obligation of confidentiality, either before or after the Receiving Party's receipt of such information.

7. TRAINING/PROCTORING.

7.1 Training. Intuitive offers training to surgical personnel on the use and operation of the System. At Purchaser's request, at mutually agreed times and at mutually agreed locations, Intuitive will provide training in the use of the System to Purchaser's surgical personnel. As of the Effective Date, the price for training is three thousand dollars (\$3,000) per surgeon or physician's assistant. The payment terms for training are net thirty (30) days from the date of Intuitive's invoice. This pricing will remain in effect during the first year of the Initial Term. Thereafter, training will be made available to Purchaser at Intuitive's then current list price for training. Notwithstanding the above, Intuitive agrees to provide training to 2 surgical personnel as set forth above, included in the price shown on Exhibit A, provided such training is completed within the first twelve (12) months of the Initial Term of this Agreement.

7.2 Proctoring. As of the Effective Date, the rate for Proctor's services is three thousand dollars (\$3,000.00) per day. The payment terms for Proctoring are net thirty (30) days from the date of Intuitive's invoice. This pricing will remain in effect during the first year of the Initial Term. Thereafter, Proctoring will be made available to Purchaser at Intuitive's then current list price for Proctoring.

8. MISCELLANEOUS.

8.1 Assignment. This Agreement shall be binding upon the permitted successors and assigns of the parties; provided, however, that no assignment shall be made by either party without the prior written consent of the other, which consent shall not be unreasonably withheld, except or

pursuant to a transfer of all or substantially all of a party's assets and business relating to the subject of this Agreement, whether by merger, sale of assets, sale of stock, or otherwise. Any attempt by either party to assign this Agreement or any rights or duties hereunder contrary to the foregoing provision shall be void. Purchaser may not assign or transfer the Software license granted to it under this Agreement to any third party without Intuitive's prior written consent, which consent will not be unreasonably withheld. Any attempt by either party to assign this Agreement or any rights or duties hereunder contrary to the foregoing provision is void. Intuitive consents to Purchaser's assignment of this Agreement to a Funding Entity as part of Purchaser's financing arrangement with the Funding Entity. If Purchaser assigns this Agreement to a Funding Entity, Purchaser retains its right to all benefits under this Agreement, including without limitation all warranties, representations, and indemnification provided by Intuitive, and may independently enforce any obligation, warranty, or representation.

8.2 Waivers. No waiver of any right by either party under this Agreement shall be of any effect unless such waiver is express, in writing and signed by the waiving party. Any purported waiver not consistent with the foregoing shall be void.

8.3 Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be invalid under any applicable statute, rule or law, the parties agree that such invalidity shall not affect the validity of the remaining provisions of the Agreement, and further agree to substitute for the invalid provision a valid provision that most closely approximates the intent and economic effect of the invalid provision.

8.4 Interpretation. Headings used in this Agreement are provided for convenience only, and shall not in any way affect the meaning or interpretation hereof. Accordingly, the language of this Agreement shall not be construed for or against either Party.

8.5 Notices. Any notices given under this Agreement must be in writing and shall be deemed given and received five (5) days after the date of mailing, one (1) day after dispatch by overnight courier service or electronic mail, or upon receipt if by hand delivery, or upon completion of transmission if by facsimile. Any notices pursuant to this Agreement shall be sent to Intuitive or the Purchaser at the address shown on the first page of this Agreement. Each party may change its address for receipt of notices by giving the other party notice of the new address.

Notices:

Intuitive Surgical:
Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086
Attention: Contracts Administration

Purchaser Ship to:
Forsyth Medical Center
3333 Silas Creek Parkway
Winston-Salem, North Carolina 27103

8.6 Force Majeure. The parties understand and acknowledge that neither party shall be liable for any loss, damage, detention, delay (provided such party uses reasonable efforts to remedy the delay as expeditiously as possible) or failure to perform in whole or in part resulting from causes beyond either party's control including, but not limited to, acts of God, acts of terrorism, fire, flood, earthquake, war, riots, labor disputes, shortage of components, or any governmental law, order, regulation or ordinance.

8.7 Confidential Nature of Agreement. The terms of this Agreement are confidential and Purchaser agrees not to disclose the terms of this Agreement to any third party without the express written consent of Intuitive.

8.8 Federal Audit. Intuitive agrees that until the expiration of four (4) years after completing its obligations pursuant to this Agreement, Intuitive shall make available upon written request of the Secretary of the Department of Health and Human Services (the "Secretary") or upon request of the U.S. Comptroller General, or any of their duly authorized representatives, this Agreement and the books, documents and records of Intuitive that are necessary to certify the nature and extent of costs for which Purchaser may properly seek reimbursement. Intuitive further agrees that if Intuitive carries out any of the duties of this Agreement through a subcontract with a value or cost of ten thousand dollars (\$10,000) or more over a twelve (12) month period, such subcontract shall contain a clause to the effect that until the expiration of four (4) years after completing its duties pursuant to such subcontract, the subcontracting party shall make available, upon written request of the Secretary, or upon request of the U.S. Comptroller General or any of their duly authorized representatives, the subcontract, and the books, documents, and records of such organization that are necessary to verify the nature and extent of such costs. Intuitive shall promptly inform Purchaser of any requests for information made pursuant to this provision.

8.9 Debarment. Intuitive warrants and represents that neither Intuitive nor any of the individuals of their organization involved in meeting the performance of obligations under this Agreement have been convicted of any criminal offense relating to health care and are not debarred, excluded or otherwise ineligible for participation in any federal or state health care program nor have they been convicted of a criminal offense related to the provision of health care items or services. Intuitive agrees that if at any time before completion of this Agreement it or any individual in their organization involved in completing the obligations under this Agreement is so convicted or is debarred, excluded or otherwise determined to be ineligible, as set forth herein, it will forthwith notify Purchaser in writing of such event and such individual shall immediately cease its involvement under this Agreement and Intuitive will replace such individual with a replacement employee reasonably suitable to Purchaser, and, if it is Intuitive, such event shall be considered a material breach by Intuitive subject to the provisions of Section 3.

8.10 Insurance. Intuitive represents that it carries insurance as described herein: Commercial General Liability Insurance including coverage's for contractual liability, product liability, personal injury and bodily injury in an amount not less than \$1,000,000 per occurrence/\$3,000,000 aggregate. Intuitive shall furnish the Purchaser with a certificate of insurance evidencing the coverage's as outlined above at the request of the Purchaser. Intuitive shall carry Workers' Compensation Insurance as required by California State Law.

8.11 Relationship of the Parties. The parties understand and agree that their relationship hereunder is one of contract, and that they are not and shall not be construed as partners, joint venturers, or agent and principal. In no event shall either party be authorized to act for or on behalf of the other party.

8.12 Costs. Except as otherwise specifically provided herein, each party shall bear its own costs and expenses incurred in connection with the performance of its obligations hereunder.

8.13 Taxes. Any taxes, levies or similar governmental charges, now in force or enacted in the future, however, designated ("Taxes") including related penalties and interest, imposed by any governmental authority on or measured by the activities described herein shall be paid by Purchaser in

addition to the prices invoiced. Purchaser shall pay, or reimburse Intuitive for the payment of all Taxes including related penalties and interest, except Taxes for which Purchaser has provided a certificate of exemption acceptable to both Intuitive and the appropriate taxing authority, prior to shipment of the System.

8.14 Counterparts. This Agreement may be executed in multiple copies, each of which shall be deemed an original, and all of which taken together will constitute one single agreement.

8.15 Compliance with Laws. Each party agrees to comply with all applicable federal, state, and local laws and regulations in performing its obligations and undertakings under this Agreement and has and will maintain throughout the term of this Agreement all licenses, registrations, permits and certifications required by the services it provides hereunder.

8.16 Data Use. Purchaser agrees that Intuitive and its affiliates within the Intuitive Surgical group of companies (collectively, "Intuitive") may collect data relating to the use of Intuitive products ("Data"). In some instances Data may be communicated via data gathering or transmission technology to Intuitive. In other instances, Intuitive may require Purchaser and Purchaser agrees to provide Data to Intuitive. Such Data may be used for a variety of purposes, including, but not limited to (1) providing support and preventative maintenance of Intuitive products, (2) improving Intuitive products or services, (3) ensuring compliance with applicable laws and regulations, and (4) providing a general resource for Intuitive's research and business development. Intuitive does not intend to collect protected health information (PHI) as defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and associated laws and regulations, as may be amended from time to time. In the event any Data communicated to Intuitive identifies an entity or individual, Intuitive will not share such Data with any third parties without the entity's or individual's consent, unless required by law.

8.17 Privacy and Securities Policies. At all times during the term of this Agreement, Intuitive shall comply with: (1) all applicable federal, and state laws, rules, and requirements for the protection of the privacy and security of patient information, including without limitation, the Privacy and Security Rules of the Health Care Information and Portability Act and (2) all of Purchaser's policies and procedures regarding data access, security, and privacy, provided the Purchaser disclose such policies to Intuitive. Any violations or disregard of such policies, procedures, laws, rules, and regulations shall be cause for a denial of access by Intuitive's personnel to Purchaser's premise, in addition to all other rights and remedies afforded to Purchaser under this Agreement or such applicable laws rules and regulations.

8.18 Entire Agreement; Amendment. This Agreement sets forth the entire agreement between Intuitive and Purchaser with respect to the subject matter hereof and supersedes any prior agreements, understandings promises and representations made orally or in writing by either party, to the other party, concerning the subject matter herein, pricing and the applicable terms. Any terms or conditions contained in Purchaser's (or as applicable, Funding Entity's) purchase order which are different from, inconsistent with or in addition to the terms and conditions of this Agreement shall be void and of no effect, unless otherwise mutually agreed to in writing by the parties. This Agreement may be amended only in writing, signed by both parties. Any purported oral modification intended to amend the terms and conditions of this Agreement shall be void.

IN WITNESS THEREOF, both Parties acknowledge they have read, understand and agree to be bound by the terms and conditions of this Agreement and as authorized signatories agree have executed this Agreement as of the Effective Date set forth above.

ACCEPTED BY:
INTUITIVE SURGICAL, INC.

ACCEPTED BY:
FORSYTH MEMORIAL D/B/A/ FORSYTH
MEDICAL CENTER

Signature: Larry E. Crist
Larry E. Crist (Jun 12, 2012)

Email: larry.crist@Intusurg.com

Title: Director, Contracts Administration

Company: Intuitive Surgical, Inc.

By: _____

Name: _____

Title: _____

Date: _____

Jun 11, 2012

KH
KH

EXHIBIT A
Deliverables, Price and Delivery

1. Intuitive will provide Purchaser with the following: da Vinci[®] Si™ Surgical System (with single console)
Equipment List

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
Warranty period: One (1) year from the Acceptance date.

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
Warranty period: One (1) year from the Acceptance date.

System Vision Cart

Warranty period: One (1) year from the Acceptance date.

System Documentation including: User's Manual For System

Warranty period: Not Applicable.

System Software

Warranty period: One (1) year from the Acceptance date.

Instrument and Accessory: Reusable Accessory Starter Kit (Starter Kit contents subject to change without notice)

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): Box of 10: 8mm Cannula Seals
One (1): Box of 3: 8mm Cannula
One (1): Cannula Gage Pin
One (1): Blunt Obturator
One (1) Box of 24: Bladeless Obturator
One (1): Blade Protector
One (1): Allen Wrench
One (1): Spare Lamp Module
Warranty period: Ninety (90) days from the Acceptance date

Instrument and Accessory: Camera Starter Kit: (Starter Kit contents subject to change without notice)

One (1): 3D-HD Camera Head with Light Guide
One (1): Camera Cable
One (1): 0 degree Endoscope
One (1): 30 degree Endoscope
One (1): Alignment Target
Warranty period: One (1) year from the Acceptance date.

Instrument and Accessory: Training Instrument Starter Kit (Starter Kit contents subject to change without notice)

- One (1): Large Needle Driver
- One (1): ProGrasp™ Forceps
- One (1): Maryland Bipolar Forceps
- One (1): Curved Scissors
- One (1): Tenaculum Forceps
- One (1): Suture Cut Needle Driver

Warranty period: One (1) year from the Acceptance date.

2. **Pricing.** All amounts are shown in US Dollars.

System Type	Quantity	Price	Delivery Fees
da Vinci® SI™ Surgical System (with single console)	1	\$725,000	Included

It is Customer's responsibility to determine whether this purchase complies with Customer's State's Certificate of Need laws and what Certificate of Need filing, if any, needs to be made with regard to this purchase.

*The Delivery Date is an estimated "on or before" delivery date to Purchaser's designated location (see "Ship-to" below).

3. **Trade-In of System.** "Trade-in System" means the da Vinci® Surgical System purchased from Intuitive with a serial number of S00381 and
- 1 camera head(s),
 - 3 endoscope(s) (0 degree),
 - 2 endoscope(s) (30 degree).

Purchaser represents and warrants to Intuitive that as of the date of Acceptance, it has clear title to the Trade-in System. Within 30 days after Acceptance, Purchaser will provide access to the Trade-in System at Purchaser's site to enable Intuitive to disconnect and remove the Trade-in System.

Purchaser acknowledges that any Service amounts paid to Intuitive for the Trade-in System are non-refundable.

4. **Return of Instruments and Accessories.** Instruments or accessories ("I/A") may be returned by Purchaser to Intuitive in accordance with Intuitive's policy for such returns as set forth in Intuitive's then current Instruments and Accessory Price List ("I/A Price List"). Products that are damaged due to misuse, mishandling or negligence and/or products which were shipped to Purchaser more than 12 months prior to the return request will not be accepted for returns.

Notwithstanding anything to the contrary regarding shipping fees and restocking fees in the I/A Price List, for I/A for the Trade-in System only, Intuitive will waive shipping charges and standard re-stocking fees for I/A returns that meet all of the following conditions:

- maximum of \$50,000 (purchase price) of I/A, and
- RMA number issued to Purchaser during the thirty (30) days after the Delivery Date in accordance with the procedure in the I/A Price List, and I/A returned to Intuitive within 14 days of RMA issuance, and
- all I/A must be unexpired, and in new, unopened, seals-intact packaging.

PROPOSED CAPITAL COSTS

Attachment C

Project Name: Da Vinci Surgical System Robotic Unit for Forsyth Medical Center, Women's Center ORs

Proponent: Forsyth Medical Center, Winston-Salem, NC

A. <u>Site Costs</u>		
(1)	Full purchase price of land.....	\$
	Acres _____ Price per Acre \$ _____	
(2)	Closing costs.....	\$
(3)	Site Inspection and Survey.....	\$
(4)	Legal fees and subsoil investigation	\$
(5)	Site Preparation Costs	
	Soil Borings	\$
	Clearing-Earthwork.....	\$
	Fine Grade For Slab.....	\$
	Roads-Paving.....	\$
	Concrete Sidewalks.....	\$
	Water and Sewer.....	\$
	Footing Excavation.....	\$
	Footing Backfill.....	\$
	Termite Treatment.....	\$
	Other (Specify)	\$
	Sub-Total Site Preparation Costs.....	\$
(6)	Other (Specify)	\$
(7)	Sub-Total Site Costs	\$ 0
B. <u>Construction Contract</u>		
(8)	Cost of Materials	
	General Requirements	
	Concrete/Masonry	
	Woods/Doors & Windows/Finishes	
	Thermal & Moisture Protection	
	Equipment/Specialty Items	
	Mechanical/Electrical	
	Other (Specify)	
	Sub-Total Cost of Materials.....	\$
(9)	Cost of Labor	\$
(10)	Other (Specify)	\$
(11)	Sub-Total Construction Contract.....	\$ 0
C. <u>Miscellaneous Project Costs</u>		
(12)	Building Purchase.....	\$
(13)	Fixed Equipment Purchase/Lease	\$
(14)	Movable Equipment Purchase/Lease	\$ 725,000
(15)	Furniture	\$
(16)	Landscaping.....	\$
(17)	Consultant Fees	
	Architect and Engineering Fees	\$
	Legal Fees.....	\$
	Market Analysis.....	\$
	Other (Specify)	\$
	Other (Specify)	\$
	Sub-Total Consultant Fees.....	\$
(18)	Financing Costs (e.g. Bond, Loan, etc.).....	\$
(19)	Interest During Construction	\$
(20)	Other (Specify).....	\$
(21)	Sub-Total Miscellaneous	\$ 0
(22)	Total Capital Cost of Project (Sum A-C above).....	\$ 725,000

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June 11, 2012

Mr. Marty Haynes
Strategic Sourcing Manager
Novant Health
119 Brookstone Avenue, Suite 400
Winston-Salem, NC 27101

RE: Forsyth Medical Center
Purchase of da Vinci Robotic® SI™ Surgical System

Dear Mr. Haynes:

Thank you for your consideration of the daVinci® SI™ Surgical System.

By receipt of this letter, FMC understands that the quotation requires trade in, transfer of title, and removal out-of-state of the daVinci® Surgical System, serial number S00381 which includes 2 camera heads, 2 endoscopes (0 degree) and 2 endoscopes (30 degrees) (the "Standard System") as part of your purchase of the daVinci® Si™ Surgical System. This equipment will not be returned to North Carolina. The cost for the de-installation and removal is included in the price quotation for the replacement equipment. There are no additional costs for de-installation and removal.

If you have any questions, please contact Marilyn Mastros, Sr. Contracts Negotiator, at 408-523-2233.

Sincerely,

Signature: 
Larry E. Crist (Jun 11, 2012)

Email: larry.crist@intusurg.com

Title: Director, Contracts Administration

Company: Intuitive Surgical, Inc.

File: daVinci Surgical SystemFMCWomensCntrVendorRemoveLtr.06.11.12.doc

**EQUIPMENT COMPARISON: Replacement of Forsyth Medical Center Women's Center
Da Vinci Surgical Robotic Equipment—June 2012**

Attachment E

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Surgical Robotic Equipment	Surgical Robotic Equipment
Manufacturer of Equipment	Intuitive Surgical	Intuitive Surgical
Tesla Rating for MRIs	N/A	N/A
Model Number	da Vinci Standard Surgical System	da Vinci "Si" Surgical System
Serial Number	184547	To be determined upon acquisition
Provider's Method of Identifying Equipment	Novant Fixed Asset Tag #	Novant Fixed Asset Tag #
Specify if Mobile or Fixed *NOTE: it will be used in the FMC Women's Center ORs; the unit is on wheels, but will not move around to different hospitals as with a mobile MRI scanner	Mobile*	Mobile*
Mobile Trailer Serial Number/VIN #	NA	NA
Mobile Tractor Serial Number/VIN #	NA	NA
Date of Acquisition of Each Component	Jan. 2006	~June 2012
Dues Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title held by FMC upon purchase
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form for Replacement Equipment>	\$729,767	\$725,000
Total Cost of Equipment	\$729,767	\$725,000
Fair Market Value of Equipment	NA	NA
Net Purchase Price of Equipment	NA	NA
Locations Where Operated	FMC Women's Center ORs	FMC Women's Center ORs
Number Days In Use/To Be Used in N.C. Per Year	365 Days; available in OR every day	365 Days; available in OR every day
Percent of Change in Patient Charges (by Procedure)	NA	NA
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	NA
Type of Procedures Currently Performed on Existing Equipment	Minimally invasive surgical procedures using robotic surgical unit	NA
Type of Procedures New Equipment is Capable of Performing	NA	Minimally invasive surgical procedures using robotic surgical unit