



Certificate of Need Program EQUIPMENT REPLACEMENT APPLICATION

-Expedited review if equipment to be replaced was CON-approved.
-Full review if equipment was not CON-approved.



Project Name: Saint Luke's Hospital Project No: 5949 HT

Project Description: Replace current da Vinci Si System (previous approved CON #5074 HS) with the da Vinci Xi System

Done Page N/A Description

Divider I. Application Summary:

- 3 1. Applicant Identification and Certification (Form MO 580-1861)
- 4 2. Representative Registration (From MO 580-1869)
- 5 3. Proposed Project Budget (Form MO 580-1863) and detail sheet with documentation of costs.

Divider II. Proposal Description:

- 8 1. Provide a complete detailed project description and include the type/brand of the existing equipment and the replacement equipment.
- 8 2. Provide a listing with itemized costs of the medical equipment to be acquired and bid quotes.
- 8 3. Provide a timeline of events for the project, from CON issuance through project completion.

Divider III. Service Specific Criteria and Standards:

- 9 1. Describe the financial rationale for the proposed replacement equipment.
- 9 2. Document if the existing equipment has exceeded its useful life.
- 9 3. Describe the effect the replacement unit would have on quality of care.
- 9 4. Document if the existing equipment is in constant need of repair.
- 9 5. Document if the lease on the current unit has expired.
- 9 6. Describe the technological advances provided by the new unit.
- 10 7. Describe how patient satisfaction would be improved.
- 10 8. Describe how patient outcomes would be improved.
- 10 9. Describe what impact the new unit would have on utilization.
- 10 10. Describe any new capabilities that the new unit would provide.
- 10 11. By what percent will this replacement increase patient charges.

(If replacement equipment was not previously approved, also complete Divider IV below.)

Divider IV. Financial Feasibility Review Criteria and Standards:

- 1. Document that sufficient financing is available by providing a letter from a financial institution or an auditor's statement indicating that sufficient funds are available.
- 2. Provide Service-Specific Revenues and Expenses (Form MO 580-1865) projected through three (3) **FULL** years beyond project completion.
- 3. Document how patient charges are derived.
- 4. Document responsiveness to the needs of the medically indigent.

Divider I. Application Summary:

1. Applicant Identification and Certification (Form MO 580-1861).

The required Application Identification and Certification form (Form MO 580-1861) is included in this application on Exhibit I-1 (on page 3).

2. Representative Registration Form (Form MO 580-1869).

The Representative Registration form (Form MO 580-1869) is included in this application on Exhibit I-2 (on page 4).

3. Proposed Project Budget (Form MO 580-1863).

The Proposed Project Budget form (Form MO 580-1863) is included in this application on Exhibit I-3 (on page 5).



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APPLICANT IDENTIFICATION AND CERTIFICATION

The information provided must match the **Letter of Intent** for this project, without exception.

1. Project Location *(Attach additional pages as necessary to identify multiple project sites.)*

Title of Proposed Project Saint Luke's Hospital	Project Number 5949 HT
Project Address <i>(Street/City/State/Zip Code)</i> 4401 Wornall Road Kansas City, MO 64111	County Jackson

2. Applicant Identification *(Information must agree with previously submitted Letter of Intent.)*

List All Owner(s): <i>(List corporate entity.)</i>	Address <i>(Street/City/State/Zip Code)</i>	Telephone Number
Saint Luke's Hospital	4401 Wornall Road Kansas City, MO 64111	(816) 932-2000
<i>(List entity to be licensed or certified.)</i>		
List All Operator(s): <i>(List entity to be licensed or certified.)</i>	Address <i>(Street/City/State/Zip Code)</i>	Telephone Number
Saint Luke's Hospital	4401 Wornall Road Kansas City, MO 64111	(816) 932-2000

3. Ownership *(Check applicable category.)*

- Nonprofit Corporation
 Individual
 City
 District
 Partnership
 Corporation
 County
 Other _____

4. Certification

In submitting this project application, the applicant understands that:

- (A) The review will be made as to the community need for the proposed beds or equipment in this application;
- (B) In determining community need, the Missouri Health Facilities Review Committee (Committee) will consider all similar beds or equipment within the service area;
- (C) The issuance of a Certificate of Need (CON) by the Committee depends on conformance with its Rules and CON statute;
- (D) A CON shall be subject to forfeiture for failure to incur an expenditure on any approved project six (6) months after the date of issuance, unless obligated or extended by the Committee for an additional six (6) months;
- (E) Notification will be provided to the CON Program staff if and when the project is abandoned; and
- (F) A CON, if issued, may not be transferred, relocated, or modified except with the consent of the Committee.

We certify the information and date in this application as accurate to the best of our knowledge and belief by our representative's signature below:

5. Authorized Contact Person *(Attach a Contact Person Correction Form if different from the Letter of Intent.)*

Name of Contact Person Myles Ortiz	Title Operations Project Consultant
Telephone Number (816) 599-9448	Fax Number E-mail Address mylortiz@saintlukeskc.org
Signature of Contact Person 	Date of Signature 05/09/2022



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REPRESENTATIVE REGISTRATION

(A registration form must be completed for **each** project presented.)

Project Name Saint Luke's Hospital		Number 5949 HT	
<i>(Please type or print legibly.)</i>			
Name of Representative Myles Ortiz		Title Operations Project Consultant	
Firm/Corporation/Association of Representative (may be different from below, e.g., law firm, consultant, other) Saint Luke's Health System		Telephone Number (816) 932-2000	
Address (Street/City/State/Zip Code) 901 E. 104th St., Kansas City, MO 64131			
Who's interests are being represented? <i>(If more than one, submit a separate Representative Registration Form for each.)</i>			
Name of Individual/Agency/Corporation/Organization being Represented Saint Luke's Hospital (Kansas City)		Telephone Number (816) 932-2000	
Address (Street/City/State/Zip Code) 4401 Wornall Road, Kansas City, MO 64111			
<p>Check one. Do you:</p> <p><input checked="" type="checkbox"/> Support</p> <p><input type="checkbox"/> Oppose</p> <p><input type="checkbox"/> Neutral</p> <p>Other Information:</p> <p>_____</p> <p>_____</p>		<p>Relationship to Project:</p> <p><input type="checkbox"/> None</p> <p><input checked="" type="checkbox"/> Employee</p> <p><input type="checkbox"/> Legal Counsel</p> <p><input type="checkbox"/> Consultant</p> <p><input type="checkbox"/> Lobbyist</p> <p><input type="checkbox"/> Other (explain):</p> <p>_____</p> <p>_____</p>	
<p>I attest that to the best of my belief and knowledge the testimony and information presented by me is truthful, represents factual information, and is in compliance with §197.326.1 RSMo which says: <i>Any person who is paid either as part of his normal employment or as a lobbyist to support or oppose any project before the health facilities review committee shall register as a lobbyist pursuant to chapter 105 RSMo, and shall also register with the staff of the health facilities review committee for every project in which such person has an interest and indicate whether such person supports or opposes the named project. The registration shall also include the names and addresses of any person, firm, corporation or association that the person registering represents in relation to the named project. Any person violating the provisions of this subsection shall be subject to the penalties specified in §105.478, RSMo.</i></p>			
Original Signature		Date	
<p>DocuSigned by:</p> <p>99576646362F49B...</p>		05/09/2022	



Certificate of Need Program

PROPOSED PROJECT BUDGET

Description

Dollars

COSTS:*

(Fill in every line, even if the amount is "\$0".)

1. New Construction Costs ***	\$0
2. Renovation Costs ***	\$0
3. Subtotal Construction Costs (#1 plus #2)	\$0
4. Architectural/Engineering Fees	\$0
5. Other Equipment (not in construction contract)	\$0
6. Major Medical Equipment	\$2,459,500
7. Land Acquisition Costs ***	\$0
8. Consultants' Fees/Legal Fees ***	\$0
9. Interest During Construction (net of interest earned) ***	\$0
10. Other Costs ***	\$0
11. Subtotal Non-Construction Costs (sum of #4 through #10)	\$2,459,500
12. Total Project Development Costs (#3 plus #11)	\$2,459,500 **

FINANCING:

13. Unrestricted Funds	\$2,459,500
14. Bonds	\$0
15. Loans	\$0
16. Other Methods (specify)	\$0
17. Total Project Financing (sum of #13 through #16)	\$2,459,500 **

18. New Construction Total Square Footage	0
19. New Construction Costs Per Square Foot *****	\$0
20. Renovated Space Total Square Footage	0
21. Renovated Space Costs Per Square Foot *****	\$0

* Attach additional page(s) detailing how each line item was determined, including all methods and assumptions used. Provide documentation of all major costs.

** These amounts should be the same.

*** Capitalizable items to be recognized as capital expenditures after project completion.

**** Include as Other Costs the following: other costs of financing; the value of existing lands, buildings and equipment not previously used for health care services, such as a renovated house converted to residential care, determined by original cost, fair market value, or appraised value; or the fair market value of any leased equipment or building, or the cost of beds to be purchased.

***** Divide new construction costs by total new construction square footage.

***** Divide renovation costs by total renovation square footage.



Intuitive Surgical, Inc.
 1020 Kifer Road
 Sunnyvale, CA 94086
 800-876-1310

Quote Details

Quote ID	171686.0
Quote Date	3/21/2022
Valid Until	3/31/2022
Sales Rep	Lisa Spoonhour
Phone Number	1(913) 284-1866
Email	Lisa.Spoonhour@intusurg.com

Company Information

Hospital Name	St. Luke's Hospital of Kansas City
SF ID / IDN Affiliation	10124/Saint Luke's Health System - Kansas City
Address	4401 Wornall Rd
City, State, Zip	Kansas City, MO, 64111
Contact Name	
Telephone	

Please submit orders electronically via GHX or fax to 408-523-2377

Items

Part Number	Qty	Item	Price	Subtotal
da Vinci Systems				
	1	da Vinci Xi® Dual Console System Two (2): da Vinci Xi System Surgeon Consoles One (1): da Vinci Xi System Patient Cart One (1): da Vinci Xi System Vision Cart da Vinci Xi System Documentation da Vinci Xi System Software Training Instrument Starter Kit Accessory Starter Kit Drapes Vision Equipment (All Kits subject to change without notice)	\$2,350,000.00	\$2,350,000.00
da Vinci System Upgrades				
	1	da Vinci® Xi® Integrated Table Motion Sold with System Upgrade includes: - Table Connection hardware module for patient cart - Integrated Table Motion software Upgrade Note: Integrated Table Motion requires connection to a Trumpf Medical TruSystem 7000dV operating table for feature use. The TruSystem 7000dV operating table is sold and serviced by Trumpf Medical.	\$75,000.00	\$75,000.00
	1	E-100 generator is a bipolar electrosurgical unit (ESU) used with compatible dV instruments - SynchroSeal and VSE	\$25,000.00	\$25,000.00
Freight				
	1	System Freight - Central (AR, IA, IL, KS, LA, MN, MO, ND, NE, OK, SD, TX, WI)	\$9,500.00	\$9,500.00
Total				\$2,459,500.00

Service

Part Number	Qty	Item	Price	Subtotal
	1	Da Vinci Xi® dVComplete Care Service Plan (dual console) Years 2-5, per year	\$179,000.00	\$179,000.00
	1	Year One System Service (Included in System Fee unless an amount is listed)	\$0.00	\$0.00

Terms and Conditions

1) System Terms and Conditions:

1.1 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. Delivery is subject to credit approval. 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 price of the da Vinci® Surgical System includes the initial installation of the System at Customer's facility and a one (1) year warranty for manufacture defect. All taxes and shipping charges are the responsibility of the Customer and will be added to the invoice, as appropriate.

1.2 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.

1.3 Customer acknowledges that the cleaning and sterilization equipment, not provided by Intuitive, is required to appropriately reprocess da Vinci instruments and endoscopes. Please refer to the Intuitive Surgical Reprocessing website: <https://reprocessing.intuitivesurgical.com>. Customer is responsible for ensuring that its' cleaning and sterilization program comply with

all health and safety requirements.

2) System Upgrade Terms and Conditions:

2.1 A signed Purchase Order and/or an addendum to the existing Sales, License, and Service Agreement ("SLSA") is required prior to shipment of the System upgrade. All site modifications and preparation are the Customer's responsibility and are to be completed with the specification given by Intuitive Surgical prior to the installation date.

2.2 Payment terms are net 30 days from Intuitive Surgical's invoice date. The price includes: the System upgrade, the initial installation at Customer's facility and a one (1) year warranty for manufacture defect. All taxes and shipping charges are the responsibility of the Customer and will be added to the invoice, as appropriate. Delivery is subject to credit approval and inventory availability. Standard shipping terms are FCA from Intuitive Surgical™ warehouse. A \$9.95 handling charge will be applied for any shipments using a customer designated carrier.

3) Intuitive Hub Terms and Conditions:

3.1 A signed agreement or addendum to the existing system agreement according to Section A.1.1 above is required prior to shipment of INTUITIVE's Intuitive Hub. All site modifications and preparation are the Customer's responsibility and are to be completed with the specification given by INTUITIVE prior to the installation date.

3.2 Payment terms are net 30 days from INTUITIVE's invoice date unless agreed differently in writing by the parties. The price includes: INTUITIVE's Intuitive Hub and the initial installation at Customer's facility. All taxes and shipping charges are the responsibility of the Customer and will be added to the invoice, as appropriate.

Intuitive recommends discussing with your IT department the customer-provided infrastructure requirements prior to purchase:

- Windows Server OS license for Web/Application server
- Microsoft MS-SQL database
- Initial storage allocation of approximately 1-2 TB per system
- Storage allocation may vary with system utilization, procedure volume, and customer-driven retention policy

4) I&A Terms and Conditions:

4.1 To place an order, please fax Purchase Order to Intuitive Surgical Customer Service at 408-523-2377 or submit through the Global Health Exchange (GHX). Payment Terms Net 30 Days from invoice date. Delivery is subject to credit approval by Intuitive Surgical. Estimated 2-Day standard delivery. Standard shipping terms are FCA from Intuitive Surgical™ warehouse and are subject to inventory availability. Pricing is subject to applicable shipping costs and taxes. Pricing is subject to change without notice. A \$9.95 handling charge will be applied for any shipments using a customer designated carrier.

5) Return Goods Policy :

5.1 All returns must be authorized through Intuitive Surgical Customer Service, please call 800-876-1310 to obtain a Return Material Authorization Number (RMA#). All items must be accompanied with valid RMA# for processing and are requested to be received within 14 days of issuance or the RMA could be subject to cancellation. Intuitive Surgical will prepay for the return of the defective instruments. Upon identification of a defective instrument, please call Intuitive Surgical Customer Service within 5 business days. Prior to returning to Intuitive Surgical, items must be cleaned and decontaminated in accordance with the then current local environmental and safety laws and standards. For all excess inventory returns, items are required to be in the original packaging with no markings, seals intact, and to have been purchased within the last 12 months. Package excess returned inventory in a separate shipping container to prevent damage to original product packaging.

6) Exchange Goods Policy :

6.1 Repairs to Endoscope, Camera Head and Skills Simulators may qualify for Intuitive Surgical advanced exchange program. Please contact Customer Service or send email to CustomerSupport-ServiceSupport@intusurg.com to obtain information on our current exchange program.

7) Credit Policy :

7.1 Intuitive Surgical will issue credit against original purchase order after full inspection is complete. Credit for defective returns: Intuitive Surgical will issue credit on products based on failure analysis performed and individual warranty terms. For instruments, credit will be issued for the remaining lives, plus one additional life to compensate for usage at the time the issue was identified. Evidence of negligence, misuse and mishandling will not qualify for credit. Credit for excess inventory returns: Excess Inventory returns will be valued at the invoice price. Original packaging must be unmarked, undamaged and seals intact to qualify for credit. Credit will be issued if the products were shipped less than 12 months prior to return request, the original package is intact and the product is within expiration date. Intuitive Surgical will retain all returned product.

8) Miscellaneous :

8.1 Warranty: Warranties are applied for manufacturing defects. Endoscope, Camera, Simulator, and System upgrades – 1 year warranty. Accessories – 90 day warranty. Instruments: see above for credit.

8.2 Any term or condition contained in your purchase order or similar forms which is different from, inconsistent with, or in addition to these terms shall be void and of no effect unless agreed to in writing and signed by your authorized representative and authorized representative of Intuitive Surgical.

The terms and conditions of this quote, including pricing, are confidential and proprietary information of Intuitive Surgical and shall not be disclosed to any third party without the consent of Intuitive Surgical.

For questions please contact Customer Service at 800-876-1310

Divider II. Proposal Description:

1. Provide a complete detailed project description and include the type/brand of the existing equipment and the replacement equipment.

Saint Luke's Hospital of Kansas City, an entity of Saint Luke's Health System, has provided a wide range of medical services for over 130 years. This current project is to replace the da Vinci Si Robotic Surgical system with an upgraded da Vinci Xi Robotic Surgical system.

The existing unit was approved in 2014 under CON# HS-5074.

The total cost of this project is \$2,459,500.00. An equipment quote is included in this application.

2. Provide a listing with itemized costs of the medical equipment to be acquired and bid quotes.

An itemized quote for the da Vinci Xi Robotic Surgical system is included in this application as exhibit 1-4 (on pages 6-7).

3. Provide a timeline of events for the project, from CON issuance through project completion.

Once approved, we plan to complete equipment purchase and installation will occur during the 3rd quarter of 2022. The existing unit will be retired upon installation. At no time will both units be operating at the same time.

Divider III. Service Specific Criteria and Standards

1. Describe the financial rationale for the proposed replacement equipment.

While the existing *da Vinci Si* system is in functioning condition, the replacement of the existing system would advance our instrumentation, vision, and newer features like integrated table motion, natural extension of the surgeons' eyes and hands with substantially improved vision, fast four-quadrant surgery, and has scalable platforms for all the existing and new technologies provided. The setup automation and guidance would promote OR efficiency, and align with Saint Luke's Vision and Mission of serving the Kansas City community.

2. Document if the existing equipment has exceeded its useful life.

The existing system was purchased in 2014 after being approved under CON #HS-5074 and has been discontinued by the vendor. As a result, access to the disposals for the equipment is a challenge, and not sustainable. The current system is in working condition, and access to newer technologies and upgrades have been determined to be of interest and benefit for both the hospital and the patients we serve. The existing system has exceeded its current useful lifespan of 7 years.

3. Describe the effect the replacement unit would have on quality of care.

The new *da Vinci Xi* system offers the latest technologies in instrumentation, vision, access, and precision, allowing surgeons to replicate high-quality outcomes for patient cases to meet evolving industry standards.

4. Document if the existing equipment is in constant need of repair.

Not applicable; the equipment has not required constant repair.

5. Document if the lease on the current equipment has expired.

Not applicable; the existing unit was paid for in full.

6. Describe the technological advances provided by the new unit.

The fourth generation *da Vinci* surgical systems continue to advance minimally invasive surgery (MIS) across a wide spectrum of surgical procedures. Flexible configurations, upgradable architecture and a consistent interface distinguish these robots from previous generations. Standardization of instruments and components can help manage inventory and improve overall OR efficiency and patient outcomes. The attributes provided by the new unit are as follows:

- Natural extension of surgeons' eyes and hands
- Fast 4-quadrant surgery (multi-quadrant access)
- Improved vision
- Scalable platform for technologies
- Overhead boom allows the arms to rotate as a group freeing up valuable space in surgical field allow unobstructed access to the patient
- Small and lighter arms with extended range of motion to improve reach inside the body
- Endoscope (instrumentation) is easier to use – no draping, calibration, and white balance
- Allows surgeon to place scope in any of the arms to give flexibility in setup
-

7. Describe how patient satisfaction would be improved.

The *da Vinci Xi* offers improvements to the existing minimally invasive surgical techniques and standards. Patient satisfaction will be improved by potential to decrease post-operative stays, minimized recovery time, minimized scarring, and comfort knowing the most advanced technologies are being used to perform their procedure.

8. Describe how patient outcomes would be improved.

The *da Vinci* surgery is a minimally invasive surgical technique/approach that shows to have the following benefits compared to traditional open surgery:

- Short hospital stays
- Less blood loss
- Fewer complications
- Faster recovery
- Smaller incisions associated with minimal scarring

9. Describe what impact the new unit would have on utilization.

We expect to see an increase of utilization with the replacement unit because of the numerous technological advancements that will allow for increased productivity, outcomes, and satisfaction from both the surgeons and patients.

10. Describe any new capabilities that the new unit would provide

- Scope can be placed in any of the 4 arms
- Allows 4-quadrant access; allows for increased access to patient/site(s)
- *da Vinci OS4* system provides access to analytics for understanding instrument and system utilization data
- *da Vinci* operating system release adds system capability and boosts performance
- *Ergonomic settings added to assist surgeons with posture to help with fatigue and injury*

11. By what percent will this replacement increase patient charges?

No changes to patient charges are to be expected from this replacement.