Office of Health Care Access
Certificate of Need Application

Final Decision

Hospital:	**Hartford Hospital**
Docket Number:	**03-30049**
Project Title:	**Acquisition of a da Vinci™ Surgical System**
Statutory Reference:	**Sections 19a-638 and 19a-639 of the Connecticut General Statutes**
Filing Date:	**August 7, 2003**
Hearing Date:	**September 24, 2003**
Decision Date:	**October 10, 2003**
Default Date:	**November 5, 2003**
Staff Assigned:	**Laurie Greci** **Paolo Fiducia**

Project Description: Hartford Hospital ("Hospital") proposes to acquire a da Vinci™ Surgical System from Intuitive Surgical, Inc., at a total capital expenditure of $1,159,276.

Nature of Proceedings: On August 7, 2003 the Office of Health Care Access ("OHCA") received a Certificate of Need ("CON") application from Hartford Hospital ("Hospital") for the acquisition of da Vinci™ Surgical System from Intuitive Surgical, Inc., at a total capital expenditure of $1,159,276. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

A public hearing regarding the CON application was held on September 24, 2003. The Applicant was notified of the date, time, and place of the hearing. A notice to the public was published prior to the hearing in the *Hartford Courant*. Commissioner Mary M. Heffernan served as Presiding Officer for this case. The public hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure

Act (Chapter 54 of the Connecticut General Statutes) and Sections 19a-638 and 19a-639, C.G.S. The Presiding Officer heard testimony from the Applicant's witnesses and in rendering this decision, considered the entire record of the proceeding. OHCA's authority to review, approve, modify, or deny this proposal is established by Sections 19a-638 and 19a-639, C.G.S. The provisions of this section, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

Findings of Fact

Clear Public Need
Impact of the Proposal on the Hospital's Current Utilization Statistics
Proposal's Contribution to the Quality of Health Care Delivery in the Region
Proposal's Contribution to the Accessibility of Health Care Delivery in the Region

1. Hartford Hospital ("Hospital") is an acute care hospital located at 80 Seymour Street, Hartford, Connecticut. *(August 7, 2003, CON Application, page 111)*

2. The Hospital's Operating Room Department has 26 operating suites, 25 of which are currently staffed. The department's scope of service and care encompasses inpatient, ambulatory, and same-day admission patient types. *(August 7, 2003, CON Application, page 122)*

3. Surgeries at the Hospital are performed within the following categories: general surgery; urology; cardiovascular; orthopedics; gynecology; ear/nose/throat; oralmaxillofacial; neurosurgery; multisystem trauma; and organ transplantation. *(August 7, 2003, CON Application, page 122)*

4. The Hospital proposes to acquire a da Vinci™ Surgical System ("da Vinci") from Intuitive Surgical, Inc., at a total capital expenditure of $1,159,276. *(August 7, 2003, CON Application, page 1)*

5. The da Vinci is a state-of-the-art robotic surgical system that includes a surgeon's console, a surgical cart, a video cart, endoscope system, system software, system accessories, documentation and procedure-specific instrument sets. *(April 11, 2003, Facsimile, page 3)*

6. In its 510(k) Summary the Food and Drug Administration ("FDA") states that the da Vinci is intended to assist in the accurate control of instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissues including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing during general laparoscopic surgical procedures, general noncardiovascular thoracoscopic surgical procedures, and thoracoscopically-assisted cardiotomy procedures. *(November 13, 2002, 510(k) Number K022574, Indications for Use Statement , United States Food and Drug Administration)*

7. The da Vinci will allow the surgeons at the Hospital to perform minimally invasive surgery. Minimally invasive surgery is a procedure in which surgeons minimize the invasiveness of the surgery to the extent that they no longer directly touch or see the structures on which they operate. *(August 7, 2003, CON Application, page 19)*

8. The robotic system magnifies the visual field so that a surgeon can see minute differences in tissue structure. Attached to the robotic arms are the instruments that are used to cut, suture, or dissect tissue during surgery. *(August 7, 2003, CON Application, pages 21, 2, and 29)*

9. The Hospital has based the need for the da Vinci on the following:
   - The recognition that minimally invasive techniques offer improved quality of care to surgical patients.
   - Robotic surgery can provide greater surgical precision and reduce trauma and recovery time.

   (August 7, 2003, CON Application, page 2)

10. Some of the advantages of minimally invasive surgery are:
    - the reduction in the number of inpatient hospital days;
    - smaller incisions reduce the rate of occurrence of bacterial infections and blood transfusions; and
    - fewer traumas to the patient's body require less nursing care.

    (August 7, 2003, CON Application, pages 18, 20, and 23)

11. Some of the advantages of the da Vinci are:
    - the incisions required for each of the three arms of the da Vinci to enter the patient's body may be as little a one (1) centimeter;
    - the patient's post-operative pain and suffering are reduced;
    - healing time is accelerated;
    - cosmetically, patients do not bear long surgical scars;
    - the system can magnify a three dimensional view up to 25 times;
    - the computer filters any hand tremors and transmit the surgeon's every movement to the robotic arms in real time;
    - the system has a motion-scaling capability to increase precision;
    - the system provides six (6) degrees of freedom of movement; and
    - its modular design will allow upgrades as the technology advances.

    (August 7, 2003, CON Application, pages 3 and 21)

12. The Hospital is a major medical teaching and research institution and is dedicated to the investigating and enhancing patient care. The Hospital expects to add robotic surgery training as part of its graduate medical education program. *(August 7, 2003, CON Application, page 3 and 8)*

13. The da Vinci has an intensive learning curve. Surgeons will require extensive training before using the robotic technology. As part of the purchase agreement with Intuitive Surgical, Inc., two teams from the Hospital will be trained for the price of one team. Each team consists of two surgeons and two support staff. *(August 7, 2003, CON Application, page 14)*

14. Before using the da Vinci a surgeon must be experienced in laparoscopic surgery. Surgeons will first receive robotic training using inanimate models and then animate models. Each surgeon is expected to spend hours in training before using the robot in an actual case. *(August 7, 2003, CON Application, page 14)*

15. Intuitive Surgical, Inc. will teach support staff system preparation and draping, intraoperative management, troubleshooting, and cleaning and sterilization of the equipment. *(August 7, 2003, CON Application, page 178)*

16. Surgeons will visit other robotic surgery centers. Specifically, they will go to the Hackensack University Medical Center, the Food and Drug Administration ("FDA") approved da Vinci training center for the eastern United States. These trained surgeons in turn will assist in robotic surgeries to gain hands-on experience in the presence of an experienced robotic surgeon *(August 7, 2003, CON Application, page 14)*

17. The Hospital's Department of Urology recruited a urological oncologist with significant laparoscopic and robotic experience. Dr. Joseph Wagner joined the surgical staff in July 2003. Dr. Wagner has performed numerous robotic radical prostatectomies. *(August 7, 2003, CON Application, page 8)*

18. The Hospital's General Surgery department has surgeons experienced in minimally invasive surgery and expects that this will decrease their learning curve for the robotic surgery. *(August 7, 2003, CON Application, page 3)*

19. The Hospital's cardiothoracic surgeons expect to use the system for mitral valve repairs. As their training period is six to eight months, their initial use of the da Vinci will be in Spring 2004. *(August 7, 2003, CON Application, page 3)*

20. As there are no national certifications and Standards of Practice, a credentialing subcommittee of the Hospital's Perioperative Services Committee will be charged with establishing uniform criteria to be used to grant these privileges. The credentialing subcommittee will have representatives from the departments that plan to use the da Vinci: the Department of Urology; the Department of General Surgery; and the Cardiovascular Department. *(August 7, 2003, CON Application, pages 6 and 15 and Hearing Testimony of Dr. Rocco Orlando)*

21. Surgeons wishing to use the da Vinci must follow a three-step program at the Hospital. The first step is that the surgeon must have privileges to perform the surgeries using open or laparoscopic techniques. The second step is to receive the didactic training and acquire laboratory experience in the technique. The final step is to be proctored during surgery by an experienced surgeon, such as Dr. Wagner. *(Hearing Testimony of Dr. Rocco Orlando)*

22. The projected procedure volumes are based on having two surgeons from each surgical specialty of urologic, general and cardiac use the da Vinci during surgical procedures in fiscal year 2004. As the technology is still new and evolving, the projections are based on the Hospital's current intentions and available surgeons. *(August 7, 2003, CON Application, page 5)*

23. The actual volumes for fiscal years 2000, 2001, and 2002 for procedures that would benefit from the use of the da Vinci are given in the following table:

Table 1: Actual Volumes by Procedure for Fiscal Years 2000, 2001, and 2002

Procedure and ICD-9CM[1] Code Number(s)	2000	2001	2002
Urologic, Prostatectomy, 60.5	123	148	128
Cardiothoracic, Mitral Valve Repair, 35.23, 35.12, 35.96	73	68	76
General Surgery,			
Heller Myotomy[2], 42.7	8	6	5
Fundoplication[2], 44.66	46	49	36
Other	16	26	26
General Surgery Total	70	81	67
Total Number of Procedures	**266**	**297**	**271**

(August 7, 2003, CON Application, Appendix B, pages 45 to 53)

24. The projected volumes for fiscal years 2004, 2005, and 2006 using the da Vinci are given in the following table:

Table 2: Projected Volumes by Procedure for Fiscal Years 2004, 2005, and 2006

Procedure and ICD-9CM[3] Code Number(s)	2004	2005	2006
Urologic			
Prostatectomy, da Vinci, 60.5	50	75	100
Prostatectomy, non-da Vinci,	100	100	100
Urologic Total	150	175	200
Cardiothoracic			
Mitral Valve Repair, da Vinci, 35.23, 35.12, 35.96	6	18	24
Mitral Valve Repair, non-da Vinci	61	67	76
Cardiothoracic Total	67	85	100
General Surgery, da Vinci			
Heller Myotomy[4], 42.7	7	10	10
Fundoplication[2], 44.66	7	10	10
Other	7	10	10
General Surgery with da Vinci Total	21	30	30
Total Number of Procedures with da Vinci	**77**	**123**	**154**
Total Number of Procedures	**238**	**290**	**330**

(August 7, 2003, CON Application, page 55)

25. There are numerous other general surgery, cardiothoracic and urological procedures that been performed using robotics other than those listed in Table 1. Use of the da Vinci for those procedures has been limited to clinical trials. The Hospital intends to use the da Vinci for the widely accepted applications of the device, though the Hospital may also participate in clinical trials. *(Hearing Testimony of Dr. Rocco Orlando)*

[1] International Classification of Diseases (ICD), Ninth Revision, Clinical Modification (CM).
[2] A surgical procedure on the esophagus.
[3] International Classification of Diseases (ICD), Ninth Revision, Clinical Modification (CM).
[4] A surgical procedure on the esophagus.

Financial Feasibility and Cost Effectiveness of the Proposal and its Impact on the Hospital's Rates and Financial Condition

26. The capital cost for the da Vinci is $1,159,276. The Hospital's financing source will be funded depreciation. *(August 7, 2003 CON Application, page 11)*

27. The proposal will require no increase in full time equivalents. *(August 7, 2003 CON Application, page 13)*

28. The da Vinci is a mobile system that may be brought to operating rooms as needed. There will be no associated costs for construction or renovation. *(August 7, 2003 CON Application, page 15)*

29. The da Vinci will require both disposable and reusable supplies for its operation, as well as other surgical supplies that the Hospital does not currently purchase. The total supply expenses for fiscal years 2004, 2005, and 2006 are projected to be $146,753, $436,342, and $767,754, respectively. *(August 7, 2003 CON Application, pages 13 and 168)*

30. There will be a service contract that begins in the second year after purchase for $75,000 per year. The average useful life of the da Vinci is five (5) years; the useful life of additional components ranges from 4 to 7 years. Total annual depreciation will be $235,906. *(August 7, 2003 CON Application, pages 13 and 173)*

31. The Hospital's financial projection for revenue gains or losses from operations associated with the CON proposal are given in the following table:

Table 3: Hospital's Financial Projections with the CON Proposal for FY 2004, FY 2004 and FY 2005

Description	FY 2004	FY 2005	FY 2006
Revenue from Operations	$ 137,113	$663,753	$ 1,315,094
Total Operating Expense	382,659	747,248	1,078,660
Gain (Loss) from Operations	**($245,546)**	**($83,495)**	**$236,434**

(August 7, 2003 CON Application, page 172)

32. The proposal will operate at a loss for the first two years. The initially low volume of procedures will be inadequate to cover the proposal's fixed costs. An operating profit will be realized as the FDA approves additional surgical procedures for the da Vinci. *(August 7, 2003 CON Application, page 14)*

Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines

33. The following findings are made pursuant to the principles and guidelines set forth in Section 19a-637, C.G.S.:

34. There is no State Health Plan in existence at this time. *(August 7, 2003 CON Application, page 2)*

35. The proposal is consistent with Hospital's long-range plan. *(August 7, 2003 CON Application, page 2)*

36. The Hospital's proposal will augment the Hospital's teaching and research responsibilities in the areas of minimally invasive surgery and the use of robotic technology. The credentials and experience of the laparoscopic surgeons at the Hospital make the facility unique. (*August 7, 2003, CON Application, page 3)*

37. The Hospital has improved productivity and contained costs through energy conservation and group purchasing. *(August 7, 2003, CON Application, page 6)*

38. The Hospital has sufficient technical and managerial competence to provide efficient and adequate service to the public. *(August 7, 2003, CON Application, page 7)*

39. The Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs. *(August 7, 2003, CON Application, page 173)*

Rationale

Hartford Hospital ("Hospital") proposes to acquire a da Vinci™ ("da Vinci") Surgical System. The da Vinci is a state-of-the-art robotic surgical system that combines electronics and software to integrate robotic and endoscopic technologies. The da Vinci will allow the surgeons at the Hospital to perform minimally invasive surgery where the surgeon has better control and more intricate motion than currently available using standard laparoscopic instruments. This technological advancement is beneficial to patients by reducing blood loss, risk for infection and post-operative pain. The recovery time and inpatient hospital stays are in turn shortened, a benefit to the Hospital as well as to its patients.

The Hospital is a major medical teaching and research institution. Dr. Joseph Wagner, a urological oncologist and an experienced robotic surgeon is a member of the Hospital's staff. Dr. Wagner will be an integral part of the Hospital's robotic training program. The Hospital will implement a three-step credentialing program for surgeons wishing to use the da Vinci. The first step requires expertise in a procedure during open or laparoscopic surgery. Then the physician will acquire training in a laboratory setting on the da Vinci. The final step is proctoring by a surgeon experienced in the use of the da Vinci. The

purchase of the da Vinci will enable the Hospital to offer robotic surgery to its patients and include robotic surgery as part of its graduate medical education program.

This proposal will not affect other area providers as the Hospital will use this equipment to serve its existing patient base. In addition, the health care delivery system in Connecticut will benefit from this proposal as surgeries using this technology will result in shorter recovery times and shorten hospital stays.
The proposal's total capital expenditure of $1,159,276 will be funded by the Hospital's funded depreciation. There are no associated construction or renovation costs. The proposal will operate at a loss for the first two years. The initially low volume of procedures will be inadequate to cover the proposal's fixed costs. By the third year of operation, the Hospital projects to realize a profit. The number of surgeries using the da Vinci will increase as additional procedures implement the technology. The Hospital's rates are sufficient to cover the proposed capital cost and operating costs associated with the project. Therefore, OHCA concludes that the CON proposal is financially feasible. The overall value of the da Vinci is the improved patient care and the quality of the surgical services that are provided by the Hospital.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Hartford Hospital to acquire a da Vinci™ Surgical System, at a total proposed capital expenditure of $1,159,276, which does not include any capitalized financing costs, is hereby GRANTED.

Order

Hartford Hospital is hereby authorized to acquire a da Vinci™ Surgical System a total capital expenditure of $1,159,276 subject to the following conditions:

1. This authorization shall expire on October 7, 2004. The Hospital must seek further approval from OHCA if the da Vinci™ Surgical System has not been obtained by that date.

2. The Hospital shall not exceed the approved capital expenditure of $1,159,276. In the event that the Hospital learns of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of the revised project budget.

3. The Hospital shall report to OHCA the names of surgeons granted authorization by the Hospital to perform surgeries using the da Vinci™ Surgical System. The Hospital shall provide to OHCA a summary of the surgeon's training and a copy of the Curriculum Vitae.

4. The Hospital shall perform procedures that have been approved for the da Vinci™ Surgical System by the Food and Drug Administration. The numbers and types of procedures performed using the ™ Surgical System shall be reported to OHCA on a semi-annual basis calendar year basis, e.g. January through June and July through

December. The reporting period begins with the first procedure performed and extends for a period not to exceed two full calendar years. Each semi-annual filing shall be submitted to OHCA by no later than one month following the end of the reporting period. The semi-annual reports shall include the following:

- The number of procedures performed by type of procedure and by the surgeon performing the procedure;
- The number of procedures by type of procedure and by the patient's town of origin by zip code; and
- The average length of time to perform the procedures by type of procedure.

5. The Hospital may participate in clinical trials that employ the use of the da Vinci™ Surgical System. The Hospital shall submit to OHCA any reports that are prepared as a result of a clinical trial for a period not to exceed five years.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the
Office of Health Care Access

Date Signed:
October 10, 2003

Signed by:
Mary M. Heffernan
Commissioner

MMH:lkg

Table Descriptions

Table 1 lists the number of surgical procedures applicable to the proposal, for Fiscal Years 2000, 2001, and 2002. The name of the procedure and its ICD-9CM code number are listed. There were 123, 148, and 128 prostatectomies performed under ICD-9CM code number 60.5 in Fiscal Years 2000, 2001, and 2002, respectively. There were 73, 68, and 76 mitral valve repairs, including ICD-9CM code numbers 35.23, 35.12, and 35.96 in Fiscal Years 2000, 2001, and 2002, respectively. The total number of general surgery procedures were 70, 81, and 67 in Fiscal Years 2000, 2001, and 2002, respectively. The general surgery ICD-9CM code numbers included 42.7, 44.66 as well as others that are not listed. The listed procedures totaled 266, 297, 271 for Fiscal Years 2000, 2001, and 2002, respectively.

Table 2 lists the projected volumes by procedure name and ICD-9CM code number for Fiscal Years 2004, 2005, and 2006. The name of the procedure and its ICD-9CM code number are listed and the ICD-9CM codes are the same as those listed in the description for Table 1. The Hospital projects that 50, 75, and 100 prostatectomies using the da Vinci will be performed in Fiscal Years 2004, 2005, and 2006, respectively; another 100 prostatectomies are projected to be performed in each fiscal year. The Hospital projects that 6, 18, and 24 mitral valve repairs will be performed using the da Vinci in Fiscal Years 2004, 2005, and 2006, respectively; another 61, 67, and 76 will be performed without the da Vinci in Fiscal Years 2004, 2005, and 2006, respectively. For general surgery the Hospital listed only the procedures that it projects will use the da Vinci; it projects 21, 30, and 30 procedures with the da Vinci in Fiscal Years 2004, 2005, and 2006, respectively. The total number of procedures projected to be performed using the da Vinci are 77, 123, and 154 in Fiscal Years 2004, 2005, and 2006, respectively. In Fiscal Years 2004, 2005, and 2006, the Hospital projects that 238, 290 and 330 procedures will be performed; the totals include urologic procedures with and without the da Vinci, cardiothoracic procedures with and without the da Vinci and general surgery with the da Vinci.

Table 3 lists Hartford Hospital's financial projections with the Certificate of Need proposal for Fiscal Years 2004, FY 2005 and FY 2006. The expected revenue from operations is $137,113, $663,753 and $1,315,907 for Fiscal Years 2004, 2005, and 2006, respectively. The total operating expenses is projected at $382,659, $747,248, and $1,078,660 for Fiscal Years 2004, 2005, and 2006, respectively. The loss from operations in Fiscal Year 2004 and 2005 is projected to be $245,546 and $83,495, respectively. The gain from operations in Fiscal Year 2006 is projected to be $236,434.