

## Summary of Safety and Effectiveness

K072629

AUG - 6 2008

Submitter: Integrated Surgical Systems, Inc.  
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Phone Number: 916-285-9943  
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Contact Person: Russ Hibbert  
Date Submitted: September 7, 2007  
Trade Name: DigiMatch™ ROBODOC® Surgical System  
Common Name: Stereotaxic Instrument  
Device Classification: Class II  
Regulation Number: 21 CFR 882.4560

### **Substantial Equivalence Claim**

The DigiMatch™ ROBODOC® Surgical System is substantially equivalent to the Voyager/Tactile Guidance System -- CT (K052851), the Frameless Neuromate (K991081) and the da Vinci Surgical System (K043153).

### **Device Description**

The DigiMatch™ ROBODOC® Surgical System consists of the 510(k)-cleared (K960685) ORTHODOC® Preoperative Planning Workstation (ORTHODOC), and a Robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories (ROBODOC). The System (ORTHODOC and ROBODOC) is a three-dimensional graphical preoperative planner and implementation tool and is indicated as an alternative to template planning and manual broaching for treatment of patients who require primary total hip arthroplasty (THA). The ORTHODOC component of the System allows a surgeon to preoperatively assess a patient's femoral anatomy and state of hip disease, select an optimally sized femoral stem implant from a library of prostheses, and determine where the implant should be positioned within the femur. Then ROBODOC component of the System, under direct control by the surgeon, will precisely implement the preoperative plan.

### **Indications for Use / Intended Use Statement**

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch ROBODOC Surgical System is indicated for Orthopedic procedures in which the broaching/reaming in primary total hip arthroplasty (THA) may be considered to be safe and effective and where references to rigid anatomical structures may be made.

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### Comparison of Technological Characteristics and Principles of Operation

Table 1 provides a comparison of technological characteristics and principles of operation between the DigiMatch™ ROBODOC® Surgical System and its predicate devices, the Voyager/Tactile Guidance System – CT, the Frameless Neuromate and the da Vinci Surgical System.

**Table 1 Comparison of Technological Characteristics and Principles of Operation**

	<b>Patient Image Data</b>	<b>Pre-Surgical Plan</b>	<b>Surgical Plan Data</b>	<b>Machine Instructions</b>	<b>Patient/Robot Registration Requirement</b>	<b>Robot Electromechanical Arm(s)</b>
DigiMatch™ ROBODOC® Surgical System	Yes CT Scan	Yes pre-surgery	Yes high level operative plan	Yes robotic arms driven by validated control software and hardware	Yes point to surface registration	Yes Robot with single electromechanical arm and end effector implement control file instructions
Voyager Tactile Guidance System – CT (K052851)	Yes CT Scan	Yes pre-surgery	Yes high level operative plan	Yes robotic arms driven by validated control software and hardware	Yes surface to surface registration	Yes Robot with single electromechanical arm and end effector implement control file instructions
Frameless Neuromate (K991081)	Yes CT Scan	Yes pre-surgery	Yes high level operative plan	Yes robotic arms driven by validated control software and hardware	Yes fiducial marker registration	Yes Robot with single electromechanical arm and end effector implement control file instructions
da Vinci® Surgical System (K043153)	No visual image	No intra-surgery	No control file developed in real time during surgery	Yes robotic arms driven by validated control software and hardware	Yes visual registration	Yes Robot with multiple electromechanical arms and end effector implement control file instructions

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### Summary of Performance Testing

ISS has completed bench, animal, cadaver and clinical testing that assess the safety and efficacy of the ROBODOC System.

### Nonclinical Studies

Nonclinical cadaver and animal studies provide an accurate means of determining cavity accuracy and placement. The value of such studies is that they allow a measurement of the gap between the bone and implant. They also permit histological examinations of the cavity/implant interface, which has value in determining whether the implant apposition within the cavity is sufficiently narrow.

### Cadaver Study

The cadaver study compared the accuracy of cutting the femur with the ROBODOC versus manual broaching. The results showed that the ROBODOC was more accurate than manual broaching and led to significantly reduced gaps between the implant and bone.

### Animal Study

The animal study, involving 20 male greyhounds, also supports the conclusion that the ROBODOC is more accurate than manual broaching in cutting the femur. Histological examination revealed many instances of fracture or osteotomy in the control group, compared to none in the ROBODOC group. In addition, histological examination revealed that the ROBODOC group had more consistent cortical bone continuity, better apposition of implants with cortical and cancellous bone, and appeared to have less cancellous bone hypertrophy.

### Clinical Studies

The First U.S. Trial (G920035) was conducted using the "pin-based" technology, which required three locator (fiduciary) pins to register the robotic device to the patient. The primary endpoints of efficacy that demonstrated precise and reliable implantation of the preoperative plan were fit and alignment of the femoral implant. Primary clinical efficacy was demonstrated showing equivalence in Harris Hip Scores between the ROBODOC group and the manual control group.

The Second U.S. Trial (IDE # G000071) was undertaken with the "pinless" DigiMatch™ ROBODOC® Surgical System. The DigiMatch™ technology modified the ROBODOC System so as not to require pre-operative placement of fiduciary pins. The data from this trial also confirmed the safety and efficacy of the ROBODOC System. As with the First IDE Trial, primary clinical efficacy was demonstrated showing equivalence in Harris Hip Scores between the ROBODOC group and the manual control group.

### Conclusion

The DigiMatch™ ROBODOC® Surgical System, which is substantially equivalent to the Voyager/Tactile Guidance System – CT, the Frameless Neuromate and the da Vinci Surgical System, has been shown to be safe and effective for its intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG - 6 2008

Intergrated Surgical Systems, Inc.  
% Mr. Russ Hibbert  
Director, Clinical & Regulatory Affairs  
1433 N. Market Boulevard #1  
Sacramento, California 95834

Re: K072629

Trade/Device Name: DigiMatch™ ROBODOC® Surgical System  
Regulation Number: 21 CFR 882.4560  
Regulation Name: Stereotaxic instrument  
Regulatory Class: II  
Product Code: OJP, HAW  
Dated: March 31, 2008  
Received: April 3, 2008

Dear Mr. Hibbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Russ Hibbert

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): Unknown at this time K072629

Device Name: DigiMatch™ ROBODOC® Surgical System

### Indications for Use:

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

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Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number \_\_\_\_\_

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