K100314

Medacta International

MAR 3 1 2010

Special 510(k) Summary

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Date Prepared: January 29, 2010

DEVICE INFORMATION

Trade/Proprietary Name: iMNS Medacta Navigation System
Common/Classification Name:
21 CFR 882.4560
Class II
Device Product Code: HAW

Predicate Device: K083872 iMNS Medacta Navigation System

Product Description:
The iMNS Medacta Navigation System is a device for computer aided navigation of surgical instruments used in total knee replacement surgery. The system works on the common principle of stereotaxic technology in which passive markers are securely mounted on the patient's bones and an infrared camera is used to monitor the spatial location of those markers. This information is used to locate the anatomical landmarks such as centers of rotation of the femur head, knee and ankle intraoperatively. These measurements are displayed on a computer screen in real time. The instruments are then outfitted with the passive markers to improve the positioning of the cutting guides. The information from the system with the "navigated" instruments assists the surgeon in conducting the bone resections and positioning of the orthopedic surgical implants. The surgeon maintains control of the surgery and makes any decisions required with

regard to bone resections and implant positioning but the iMNS Medacta Navigation System provides real time support and information throughout the surgery.

The iMNS Medacta Navigation System consists of the following key components:

- An acquisition system composed of two infrared cameras equipped with infrared light emitting diodes (LED) to track the position of the passive markers,
- A computer running the proprietary Medacta software and a monitor,
- Interface devices of a keyboard, foot pedal and optional mouse to control the system, and
- Manual reusable surgical instruments.

The software application called GMK v4.2.2 is designed to work with Medacta's GMK Total Knee System, cleared under K090988. The manual reusable surgical instruments include instruments specifically designed for navigated surgery and other standard surgical instruments needed to conduct total knee replacement.

Indications for Use:
The iMNS Medacta Navigation System is intended to be used to support the surgeon during specific orthopedic surgical procedures by providing information on bone resections, instrument and implant positioning during joint replacement.

The iMNS Medacta Navigation System provides computer assistance to the surgeon based on anatomical landmarks and other specific data obtained intra-operatively that are used to place surgical instruments.

Examples of some surgical procedures include but are not limited to:
Total Knee Replacement
Minimally Invasive Total Knee Replacement

Performance Testing
No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act. Performance testing of the iMNS Medacta Navigation System was conducted in accordance with design controls, international standards and FDA guidance documents.

Comparison to Predicate Device
The indications for use of the modified system remain the same as the original 510(k) K083872.

The iMNS Medacta Navigation System v4.2.2 is identical to the predicate device, iMNS Medacta Navigation System v4.0 in the following aspects: Intended Use/Indications for Use, design features, operating principle, type of optical tracking system, graphical user interface, control switch, passive locators, navigated surgery process, sterility, and biocompatibility aspects.

The main difference between the iMNS Medacta Navigation System v4.2.2 and the predicate device is the software application. Previously there was only one software application, Evolis Global Femur First version 4.0 (K083872) and the second software application is GMK version 4.2.2 which is the subject of this 510(k).

The manual reusable surgical instruments have changed to those required by the non-navigated GMK Total Knee System. Additionally, there are separate micrometric positioners that are specific to GMK included with the instruments for use with navigated knee surgery and the iMNS Medacta Navigation System. These manual surgical instruments are made of the same type of materials as those in the original submission and handled the same as other reusable manual orthopedic instruments for non-navigated surgery.

The iMNS Medacta Navigation System was tested as part of design verification and validation to written protocols with pre-defined acceptance criteria. The testing met all acceptance criteria. This new software version has been completely verified and validated like an initial software release. The verification and validation activities are summarized in the below.

Summary of Design Controls for Software Changes v 4.1.0 and v 4.2.1		
Protocol ID	**Report ID**	**Title**
IL 07.09.026	EG08 and Annex 1	GUI Verification
	EG13 and Annex 1	
IL 07.09.028	EG09 EG11	Validation of resections planning and cutting blocks positioning
IL 07.09.029	EG12	Single Point/ Multi Point/ Directional Acquisition's Validation
IL 07.09.048	EG10	Functionality of the Navigation Software in Deep Stress Cases

Summary of Design Controls for Software Changes v 4.2.2		
Protocol ID	**Report ID**	**Title**
IL07.09.026	GMK00	GUI Verification
IL07.09.027	GMK06	Mechanical axis and saggital plane reconstruction
IL07.09.028	GMK02	Resection planning & cutting block positioning
IL07.09.029	GMK03	Single point/multipoint directional acquisition
IL07.09.030	GMK05	Single point acquisition
IL07.09.031	GMK01	Geometry of knee implants & ancillaries
IL07.09.092	GMK04	Validation of HW &SW compatibility & relative stability

Design validation was conducted on the iMNS Medacta Navigation System in a simulated user setting by a surgeon and demonstrated that the system meets user needs and intended uses.

There were no changes to the hardware and trolley with this device modification, there were no significant changes to the hardware system risk analysis or validation/verification.

Conclusion:
The data and information provided in this submission support the conclusion that the iMNS Medacta Navigation System (GMK v4.2.2) is substantially equivalent to its predicate device, iMNS Medacta Navigation System (Evolis v4.0) with respect to indications for use, operating principle, and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 31 2010

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Camarillo, California 93012

Re: K100314
Trade/Device Name: iMNS Medacta Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW
Dated: March 18, 2010
Received: March 22, 2010

Dear Ms. Neely:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: iMNS Medacta Navigation System

Indications for Use: K1000314

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Total Knee Replacement
Minimally Invasive Total Knee Replacement

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K1000314