JUL 12 2012

SECTION 5 - 510(K) SUMMARY OF SAFETY & EFFECTIVENESS

RENAISSANCE SYSTEM

(WITH BRAIN APPLICATION)

510(k) Number K 120812

Applicant's Name:

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Date Prepared: March 6, 2012

Name of the device: Renaissance System

Trade or proprietary name, if applicable: Renaissance System

Common or usual name: Image Guided Surgery

Establishment Registration No.: 3005075696

Classification Name: Combination of:

a. Stereotaxic Instrument; and
b. System, Image Processing, Radiological

Classification: The subject of this 510(k) is the Renaissance System, with the CFR classification sections 882.4560; Stereotaxic Instrument with product code HAW and 892.2050; System, Image Processing, Radiological and product code LLZ.

Predicate Device: The Renaissance System with Brain Application is substantially equivalent to the original Renaissance system (manufactured by Mazor Robotics Ltd., and the subject of 510(k) document no. K113228 and K110911) and to the StealthStation System (manufactured by Medtronic and the subject of 510(k) document no K050438). A comparison table and detailed discussion are presented in Section 12 of this application.

Device Description: The Renaissance System is a computer controlled miniature medical image-guided surgery (IGS) system which serves as a technological platform for solutions that provide accuracy, precision and accessibility in performing general spinal and brain procedures. The Renaissance System is designed to assist surgeons in precisely guiding handheld surgical tools and/or implants (in spinal surgery) according to a computerized, image-based, pre-operative plan along a given trajectory. The Renaissance System Brain Application was developed based on the same principles of operation for image guided brain surgeries. The Renaissance System Brain Application processes MRI and CT images via proprietary algorithms and based on the pre-operative plan the RBT Device is programmed to position its articulating arm and thus the surgical instrument at the desired coordinates. Using a special skull attachment component (i.e., the RBT Base), the RBT Device attaches to the skull in the area where the procedure is being performed, and assists surgeons in precisely positioning the handheld surgical tools according to the computerized, image-based, pre-operative plan.

The main components of the Renaissance System Brain Application include:

A. The RBT Device
B. Workstation Console in the OR and Planning PC Workstation in the physician's office
C. Renaissance Brain Application Accessories including RBT Base, Skull Screws, Guiding Arm, Star Marker, Base Screwdriver, etc.

The RBT Device and Workstation Console were previously cleared under K113228 and K110911. This 510(k) submission describes the addition of the new accessories (RBT Base, Skull Screws, Guiding Arm, Star Marker, Base Screwdriver, etc.) which enable increased accessibility for the RBT Device over the skull and the changes in the SW application.

Indication for Use:
The Renaissance System is indicated for precise positioning of surgical instruments or spinal implants during general spinal and brain surgery. It may be used in open or minimally invasive or percutaneous procedures.

Renaissance 3D imaging capabilities provide a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects.

Comparison of Technological Characteristics with the predicate device:
The modified Renaissance System with Brain Application is similar to the original Renaissance System (K113228 and K110911) and to the StealthStation System and Software (K050438) regarding indications for use. All of these devices are intended for precise positioning of surgical tools during surgery and all of these devices may be used in either open or percutaneous (i.e., minimally invasive) procedures. Furthermore, all of the above devices may be used in a surgical procedure where reference to a rigid anatomical structure, such as the spine, skull, hip, etc., can be identified relative to a CT, MR, fluoro or other image. The purpose of this 510(k) was to extend the indications for use of the original Renaissance System to include Brain Application, and thus include brain surgery procedures in which the skull (as the rigid anatomical structure) can be identified, similar to the StealthStation System. The target population (i.e., orthopedic and neurology patients), anatomical sites (i.e., any rigid anatomical structure, such as the spine or skull) and environment of use (i.e., hospital setting) are the same in the new Renaissance System with Brain Application and in the predicate devices.

The modified Renaissance System with Brain Application is identical to the original Renaissance System regarding components, design, materials, and basic scientific technology. The design of the Renaissance System with Brain Application is similar to the design of the original Renaissance System and the StealthStation System, as all systems consist of a planning and execution application and the ability to receive and merge multi-image scans. All of these devices use the same mechanism of action, i.e., computer assisted stereotaxy. The components of the modified Renaissance System with Brain Application are similar to the original Renaissance System, with the addition of new accessories to enable the brain approach, including the RBT Base, Skull Screws, Guiding Arm, Star Marker, Base Screwdriver, etc. The combination of these accessories allows trajectories and range of operation for the device in general brain surgeries. The device features and operational procedure are the same as in the original Renaissance System. Additionally, software modifications were implemented to enable the new brain approach, including a software change enabling fusion/registration between MRI and CT scans for brain procedures. The accuracy of the Renaissance System with Brain Application is the same as previously cleared Renaissance System for spine procedures, i.e., <1.5mm. The new indications for use and the technological modifications including fusion/registration between MRI and CT scans are also substantially equivalent to the StealthStation System (K050438).

Non-Clinical Performance Data

The following performance tests were conducted on the Renaissance System with Brain Application:

1. Software validation testing (IEC 60601-1-4 & FDA Guidelines)

Validation of the device software was performed according to the IEC 60601-1-4 standard and the FDA Guidance for the Content of Pre-Market Submissions for Software Contained in Medical Devices. Each software validation document was written according to the relevant IEEE standard.

The software validation documentation has been prepared for the Renaissance System with Brain Application and software version 3.4.

2. Stability Test

The objective of the Stability Test was to validate the stability of the anchoring system to the skull. The anchoring system consists of the RBT Base mounted on the skull using three Skull Screws. The stability was validated by applying forces in three different planes and measuring the resulting shift in the position of the RBT Base, as well as the pull-out force. The results demonstrated that the anchoring of the Renaissance System Brain Application is stable and pull-resistance.

3. Registration Accuracy Test

The goal of the study was to measure the accuracy of the registration method of the multimodality medical images for the Renaissance System Brain Application. The modalities in question are various types of Magnetic Resonance Imaging (MRI) scans (e.g. proton-density, T1-weighted, T2-weighted) and X-ray Computed Tomography (CT). The accuracy assessment was performed on a human head phantom. The accuracy of the registration process met the predefined device specifications.

4. Bench Accuracy Study

The objective of the study was to quantify the accumulative error of the system. This was measured based on the deviation of the tool tip from the center of the target, as well as, the measurement of the tip depth. The Renaissance System Brain Application demonstrated an overall mean accuracy of less than 1.5mm in both target plane and target depth.

5. Cadaver Accuracy Study

The aim of this study was to evaluate the system accuracy and repeatability in simulated clinical conditions, i.e., on a cadaver brain. The Renaissance System Brain Application demonstrated an overall mean accuracy of less than 1.5mm in both target plane and target depth, as well as repeatable performance.

Performance Standards:

There are no performance standards under the Federal Food, Drug and Cosmetic Act, for this type of device.

Clinical Performance Data

Not Applicable

Conclusions Drawn from Non-Clinical and Clinical Tests:

The performance tests demonstrate that Renaissance System with Brain Application may be safely and effectively used in brain surgical procedures requiring precise positioning of surgical instruments during brain surgery. The software validation and accuracy performance tests demonstrate that the Renaissance System with Brain Application meets its design and performance specifications and is substantially equivalent to the previously cleared Renaissance System.

Substantial Equivalence:

In summary, the indications for use of the modified Renaissance System with Brain Application are substantially equivalent to a combination of the original Renaissance system and the StealthStation device. Furthermore, the basic technological characteristics of the modified Renaissance System with Brain Application are identical to the original Renaissance System and similar in many respects to the StealthStation device. The differences in the technological characteristics do not raise new questions of safety and effectiveness. Consequently, the Renaissance System with Brain Application is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JUL 12 2012

Re: K120812
Trade/Device Name: Renaissance System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW and LLZ
Dated: July 4, 2012
Received: July 9, 2012

Dear Ms. Stein:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):_____

Device Name: Renaissance System

Indications for Use Statement:

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Prescription Use __√__ (Per 21 C.F.R. 801 Subpart D) OR Over-The-Counter Use___ (Optional Format Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 5120812