K112507

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MAKO SURGICAL CORP.

MAR - 1 2012

2555 davie road fort lauderdale, florida 33317 tel 954.927.2044 fax 954.927.0446

510(K) SUMMARY

Submitter:	MAKO Surgical Corp.
Address:	2555 Davie Road, Fort Lauderdale, FL, 33317
Phone number:	954-628-0655
Fax number:	954-927-0446
Contact Person:	Dionne Sanders
Date Prepared:	August 26, 2011
Device Trade Name:	Restoris Partial Knee Application (PKA)
Regulation Name:	Stereotaxic Instrument
Regulation Number:	21 CFR 882.4560
Device Classification:	Class II
Product Code:	OLO

Substantial Equivalence Claimed To: Restoris PKA is substantially equivalent to the MAKO Surgical Corp. Tactile Guidance System v2.0 a.k.a., RIO (K081867).

Description: Restoris PKA is an upgrade to the Tactile Guidance System v2.0, a.k.a RIO, which was cleared via K081867. The features of this application are to improve overall performance of the system in supporting unicondylar and/or patellofemoral knee replacement. Restoris PKA is used with RIO which includes an optical detector, robotic arm, and guidance module. In addition, the application is designed to be used with a pre-operative planning laptop, as well as both reusable and disposable instrumentation.

Restoris PKA provides stereotactic guidance during minimally invasive orthopedic surgical procedures by using patient CT data to assist a surgeon with presurgical planning and interpretive/intraoperative navigation. RIO's robotic arm, once configured for use with Restoris PKA, can serve as a surgeon's "intelligent" tool holder or tool guide by passively constraining the preparation of an anatomical site for an orthopedic implant with software-defined spatial boundaries.

Summary of Technological Characteristics Compared to Predicate Devices:
The technological characteristics of Restoris PKA compared to the predicate device are listed below:

Technological Characteristics	Restoris PKA	Tactile Guidance System v2.0 a.k.a RIO (K081867)
Major Components	Guidance module, robotic arm, camera stand, drill system, preoperative planning laptop.	Guidance module, robotic arm, camera stand, drill system, preoperative planning laptop.
Tools/accessories	Various reusable instruments e.g.., probes, arrays tracked by optical camera; disposable instruments e.g., bone-pins, checkpoints, Vizadiscs.	Various reusable instruments e.g.., probes, arrays tracked by optical camera; disposable instruments e.g., bone-pins, checkpoints, Vizadiscs.
Image Use	CT	CT

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Performance Data:
Unit, Integration and System level testing was performed with the Restoris Partial Knee Application (PKA) in order to evaluate the application's ability to support unicondylar and/or patellofemoral knee replacement. A summary of the completed design verification and validation activities to support substantial equivalence is as follows:

	Summary of Testing
Verification Testing	**Purpose** - Verification testing was completed to verify complete integration of the Restoris PKA, including all of its accessories, with the RIO platform system. **Test Method** - Sawbone models were used to run-through the procedural workflow focused on testing various aspects of the Restoris PKA with the RIO platform. **Results** - All acceptance criteria were satisfied and the test was considered passed. **Conclusion** - Integration of the Restoris PKA with the RIO platform was confirmed.
	Purpose - Verification testing was completed to verify that registration with the Restoris PKA satisfies the specified accuracy requirements. **Test Method** - Sawbone models were used to verify registration with the Restoris PKA using the software's improved bone model imaging algorithm. **Results** - All acceptance criteria were satisfied and the test was considered passed. **Conclusion** – Successful bone registration using the Restoris PKA was confirmed.
Validation Testing	**Purpose** - Validation testing was completed in a simulated-use environment with the Restoris PKA and the RIO platform to assess usability in order to confirm that the needs of the user have been met. **Test Method** - Cadaveric specimens were used to complete this validation. The procedure was completed by three (3) users with two (2) cadaveric specimens. **Results** – Testing with the Restoris PKA and the RIO platform in this validation successfully met the acceptance criteria. **Conclusion** - Testing confirmed that the Restoris PKA and the RIO platform are able to meet the needs of the user.
	Purpose – This additional validation test was conducted to assess overall system performance with emphasis on evaluating the critical steps of the PKA procedure in a more objective manner. **Test Method** - Three (3) cadaveric specimens were used to complete this validation. The procedure was performed by one surgeon with four (4) independent reviewers.

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	Results - The testing successfully met the acceptance criteria specified in the validation protocol. **Conclusion** – These testing results provided further confirmation that the Restoris PKA and the RIO platform are able to meet the needs of the user.

Intended Use/Indications for Use: The Restoris Partial Knee Application (PKA), for use with the Robotic Arm Interactive Orthopedic System (RIO), is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The Restoris Partial Knee Application (PKA), for use with the Robotic Arm Interactive Orthopedic System (RIO), is indicated for use in surgical knee procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT based model of the anatomy. These procedures include unicondylar knee replacement and/or patellofemoral knee replacement.

Substantial Equivalence: Restoris PKA has been verified and validated according to MAKO Surgical's procedures for design and development. The results of testing satisfied all required acceptance criteria and was found to support substantial equivalence of Restoris PKA to the predicate device (MAKO Surgical's Tactile Guidance System v2.0 a.k.a., RIO (K081867)).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAKO Surgical Corporation
% Ms. Dionne Sanders
Regulatory Affairs Specialist
2555 Davie Road
Fort Lauderdale, Florida 33317

MAR - 1 2012

Re: K112507
Trade/Device Name: Restoris Partial Knee Application (PKA)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: OLO
Dated: February 15, 2012
Received: February 16, 2012

Dear Ms. Sanders:

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

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INDICATIONS FOR USE

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Prescription Use ___X___ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF 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 K112507