DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 16, 2015

MAKO Surgical Corporation
Mr. Jonathan Reeves
Principal Regulatory Affairs Specialist
2555 Davie Road
Fort Lauderdale, Florida 33317

Re: K142530
Trade/Device Name: Partial Knee Application (PKA)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 8, 2015
Received: August 10, 2015

Dear Mr. Reeves:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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 -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142530

Device Name
Partial Knee Application (PKA)

Indications for Use *(Describe)*
The 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 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.

The Implant systems with which the system is compatible:
- Restoris Multicompartmental Knee System
- Restoris Porous Partial Knee System

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K142530

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:	Jonathan Reeves
Date Prepared:	Aug 29, 2014
Device Trade Name:	Partial Knee Application (PKA)
Regulation Name:	Stereotaxic Instrument
Regulation Number:	21 CFR 882.4560
Device Classification:	Class II
Product Code:	OLO

Primary Predicate Device:
Partial Knee Application is substantially equivalent to the following 510(k) cleared device:

Device Name	Manufacturer	510(k) #
RIO – PKA (Partial Knee Application)	MAKO Surgical	K112507

Additional Predicate Devices:

Device Name	Manufacturer	510(k) #
RIO – TKA (Total Knee Application)	MAKO Surgical	K143752

Device Modifications: The following modifications have been made to RIO Partial Knee Application:

- A power tool to perform the cutting for partial knee arthroplasty (MAKO Integrated Cutting System (MICS)) has been added to the system.
- Accessories (drills, burrs, blades and attachments) for the MICS cutting system have been added to the system
- A bone mineral density (BMD) phantom has been added to the system which allows the system to display the CT scan on a density scale in standard units. The BMD feature is intended to provide the surgeon with a means to assess bone density.
- Instrumentation (arrays, bone pins, gap spoons) have been modified or added to the system to improve the usability of the system
- The ability to implant the Restoris Porous implant system using the RIO system was added to the system.
- Motorized tool alignment for the RIO setup has been added to the system to improve ease of use.

- Range of motion increase on RIO to improve ease of use.

Description: Partial Knee Application is an upgrade to RIO-PKA (K112507). The features of this application are to improve overall performance of the system in supporting partial knee arthroplasty. Partial Knee Application 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.

The main RIO platform includes an optical detector, computer, dedicated instrumentation, operating software, tools and accessories, cutting system, and a robotic arm. The system's architecture is designed to support partial knee procedures. With application specific hardware and software, it 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 a specific application, can serve as 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 Partial Knee Application compared to the predicate device are listed below:

Technological Characteristics	**Partial Knee Application**	**RIO-PKA (K112507)**	**RIO-TKA (K143752)**
Major Components	Guidance Module, robotic arm, camera stand, cutting system, preoperative planning laptop.	Guidance Module, robotic arm, camera stand, cutting system, preoperative planning laptop.	Guidance Module, robotic arm, camera stand, cutting system, preoperative planning laptop.
Tools/accessories	Various reusable instruments	Various reusable instruments	Various reusable instruments
Images Use	CT	CT	CT

Intended Use/Indications for Use
The 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 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.

The Implant systems with which the system is compatible:

- Restoris Multicompartmental Knee System
- Restoris Porous Partial Knee System

Performance Data:
The Robotic Arm Interactive Orthopedic System (RIO) has been evaluated through non-clinical performance testing for:

Validation / Verification Method	Acceptance Criteria	Validation / Verification Results
MICS Handpiece Functional Test	This verification test is intended to verify the MAKO Integrated Cutting System (MICS) requirements.	Pass
MICS Attachments Functional Test	This verification test is intended to verify that the straight sagittal saw blades met applicable specifications.	Pass
RIO Base Array Functional Test	This verification test is intended to verify that the Base Array assemblies when used with the Base Array Connector meet applicable specifications.	Pass
Bone Arrays and Clamps Functional Test	This verification test is intended to verify that the array movement is equal or less than the assembly requirement to a fixed position after cutting.	Pass
PKA Application Performance Test	This verification test is intended to verify that the real time performance of the PKA application met applicable specifications.	Pass
Disposable Cutter Strength Testing	This verification test is intended to verify that the narrow saw blades met	Pass

	applicable specifications.	
Bone Mineral Density Application Functional Test	This verification test is intended to verify that the Bone Mineral Density function met applicable specifications.	Pass
Full System Run-through test	This verification test is intended to verify that the Partial Knee Application Software, and supporting instrumentation provides adequate functionality to be able to successfully complete a PKA	Pass
System Accuracy Test	The purpose of this test is to determine the overall system accuracy as a result of bone registration and bone resection accuracy. This protocol will use the verification results obtained from bone registration verification test and bone resection test and combine these results using a statistical approach.	Pass
PKA System Validation with MCK Implant system	Validate in a simulated-use environment that the integration of the Robotic Arm Interactive Orthopedic System (RIO) with the Partial Knee Application Software, MCK implant system and supporting instrumentation provides adequate functionality to successfully complete a Partial Knee Arthroplasty procedure and satisfies the customer requirements.	Pass
PKA System Validation with Restoris Porous Implant system	Validate in a simulated-use environment that the integration of the Robotic Arm Interactive Orthopedic System (RIO) with the	Pass

	Partial Knee Application Software, Restoris implant system and supporting instrumentation provides adequate functionality to successfully complete a Partial Knee Arthroplasty procedure and satisfies the customer requirements.	

Conclusions of Non-clinical Data:
The results of testing indicated the device performed within the intended use and did not raise any new safety and efficacy issues. The device was found to be substantially equivalent to the predicate device.