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

November 13, 2014

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

Re: K141989
Trade/Device Name: MAKOplasty Total Hip Application
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 8, 2014
Received: October 14, 2014

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

MAKO SURGICAL CORP®
2555 Davie Road • Ft. Lauderdale, FL 33317
Phone 954.927.2044 • Fax 954.927.0446
www.makosurgical.com

INDICATIONS FOR USE

510(k) Number: K141989

Device Name: Total Hip Application (THA)

Indications for Use:

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 RIO is indicated for use in surgical knee and hip 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
- Total hip arthroplasty (THA)

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)

2555 Davie Road • Ft. Lauderdale, FL 33317
Phone 954.927.2044 • Fax 954.927.0446
www.makosurgical.com

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:	July 03, 2014
Device Trade Name:	MAKOplasty Total Hip Application
Regulation Name:	Stereotaxic Instrument
Regulation Number:	21 CFR 882.4560
Device Classification:	Class II
Product Code:	OLO

Substantial Equivalence Claimed To: MAKOplasty Total Hip Application is substantially equivalent to MAKO Surgical's (Robotic Arm Interactive Orthopedic System) RIO – (Total Hip Arthroplasty) THA cleared via K121064.

Device Modifications:

- MAKO Integrated Cutting System (MICS)
- Inline offset cup impactor
- MICS endcap
- Reamer attachment
- 4.0mm bone pins
- RIO Base Array
- Reduction Results: hip length and combined offset

Device Description: MAKOplasty Total Hip Application is an upgrade to RIO-THA (K121064). The features of this application are to improve overall performance of the system in supporting total hip arthroplasty. MAKOplasty Total Hip 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 two main surgical applications: total hip procedures and 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 MAKOplasty Total Hip Application compared to the predicate device are listed below:

Technological Characteristics	**MAKOplasty Total Hip Application**	**RIO-THA** (K121064)
Major Components	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
Images Use	CT	CT

Intended Use/Indications for Use
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 RIO is indicated for use in surgical knee and hip 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
- Total hip arthroplasty (THA)

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

- RIO arm and MICS communication Test
- MICS Handpiece Functional Test
- MICS Cover Functional Test
- Inline Offset Cup Impactor Thread Connection Functional Test
- MICS Reamer Attachment Functional Test
- RIO Base Array Functional Test
- THA Application Performance Test
- Full System Test

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 devices.

Summary of Design Control Activities:
The risk analysis activities for this device modification include a risk management plan, hazard analysis and Failure Modes and Effects Analysis (FMEAs). Based upon the review of this data and information obtained through verification and validation activities, there are no unacceptable levels of risks that have been identified resulting from the device modification.