November 2, 2017

MAKO Surgical Corp.
Andrea Steiner
Principal Regulatory Affairs Specialist
2555 Davie Road
Fort Lauderdale, Florida 33317

Re: K172301
Trade/Device Name: Mako Partial Knee Application
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 29, 2017
Received: October 3, 2017

Dear Andrea Steiner:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
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)*

K172301

Device Name

Mako Partial Knee Application

Indications for Use *(Describe)*

The Partial Knee Application (PKA), for use with the Mako System, 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 Mako System, 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

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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510(K) SUMMARY

Sponsor: MAKO Surgical Corp.
2555 Davie Road
Fort Lauderdale, FL 33317

Contact Person: Andrea Dwyer Steiner, MS
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Phone: 954-628-0735
Fax: 954-927-0446

Date Prepared: July 28, 2017

Proprietary Name: MAKO Partial Knee Application

Common Name: 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:
The MAKO Partial Knee Application is substantially equivalent to MAKO Surgical's Partial Knee Application cleared via K170891.

Device Modifications: The following changes have been made to the MAKO Partial Knee Application:

- MICS Cutting Attachment – Addition of a 6mm burr. The burr will be used for cutting and bone resection prior to implant placement for partial knee arthroplasties

Description:
The MAKO System with the Partial Knee Application is a stereotactic instrument that includes a robotic arm, an integrated cutting system, an optical detector, a

computer, dedicated instrumentation, operating software, a planning laptop, and tools and accessories.

The system's architecture is designed to support total and partial knee procedures and total hip procedures. With application specific hardware and software, the system provides stereotactic/haptic guidance during orthopedic surgical procedures by using patient CT data to assist a surgeon with pre-surgical planning, implant placement and interpretive/intraoperative navigation of the patient's anatomy.

The MAKO 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 the MAKO Partial Knee Application compared to the predicate device are listed below:

Technological Characteristics	MAKO Partial Knee Application	MAKO Partial Knee Application (K170891)
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 and disposable instruments	Various reusable and disposable instruments
Image Use	CT	CT

Intended Use/Indications for Use:
The Partial Knee Application (PKA), for use with the MAKO System, 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 MAKO System, 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

Performance Data - The MAKO System has been evaluated through the following non-clinical performance testing:

- Cutting Accuracy Verification
- Cadaver Validation of Mako System with New Burr
- Biocompatibility Evaluation

Conclusions of Performance Testing:
The results of the performance testing demonstrate that the characteristics of the MAKO Partial Knee Application are equivalent to the predicate device, and that the device is as safe and as effective as the predicate and does not raise new questions of safety and effectiveness, and therefore supports a determination of Substantial Equivalence.