DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 18, 2017

Mako Surgical Corp.
Shikha Khandelwal
Staff Regulatory Affairs Specialist
2555 Davie Rd
Fort Lauderdale, Florida 33317

Re: K170593
Trade/Device Name: Mako Total Hip Application
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 30, 2017
Received: March 31, 2017

Dear Shikha Khandelwal:

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" (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 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,

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)*
K170593

Device Name

Mako Total Hip Application

Indications for Use *(Describe)*

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 Mako System 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)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Sponsor:
MAKO Surgical Corp.
2555 Davie Road
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Contact Person:
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Date Prepared: February 24, 2017

Proprietary Name: Mako Total Hip Application

Common Name: Total Hip Application (THA)

Regulation Name: Stereotaxic Instrument

Regulation Number: 21 CFR 882.4560

Device Classification: Class II

Product Code: OLO

Substantial Equivalence Claimed To:
The Mako Total Hip Application is substantially equivalent to Mako Surgical's Total Hip Application cleared via K141989.

Device Modification: An alternate online portal for case management and file transfer known as eRequest LifeCycle is being implemented for use during the pre-operative planning phase of the Mako Total Hip Application.

Description:
The Mako System with the Total Hip 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 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 Total Hip Application compared to the predicate device are listed below:

Technological Characteristics	Mako Total Hip Application	Mako Total Hip Application (K141989)
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 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 Mako System 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:

Validation / Verification Method	Purpose	Validation / Verification Results
Product Specification Verification	Verify that THA fields and values implemented into the eRequest application must match the THA	Pass

	Product Specifications.	
eRequest – Full System Run Through for THA Application	Verify the integration of the eRequest Lifecycle into the Mako System provides adequate functionality to successfully complete the pre-operative planning workflow	Pass
eRequest LifeCycle THA Validation	Validate in a simulated-use environment, with appropriate user, that the implementation of eRequest LifeCycle into the Mako System provides adequate functionality to successfully complete the pre-operative workflow and satisfies the customer requirements.	Pass

Conclusions of Performance Testing:
Performance testing has demonstrated that the characteristics of the Mako Total Hip Application are equivalent to the predicate device, and that the device is as safe and as effective as the predicate device and does not raise different questions of safety and effectiveness, and therefore, supports a determination of Substantial Equivalence.