July 14, 2020

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

Re: K193515
Trade/Device Name: Mako Total Knee Application
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 13, 2020
Received: July 14, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193515

Device Name
Mako Total Knee 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 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:

• Total Knee Arthroplasty (TKA)

The implant systems compatible with the system:

• Triathlon Total Knee System (CR/CS/PS/PSR cemented and cementless primary)
• Triathlon Total Knee System (TS inserts cemented primary)
• Kinetis Total Knee System (CR/UC)

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, Fort Lauderdale, FL 33317
Contact Person:	Shikha Khandelwal, PhD shikha.khandelwal@stryker.com Phone: 201-831-6921
Date Prepared:	July 14, 2020
Proprietary Name:	Mako Total Knee Application
Common Name:	Total Knee Application (TKA)
Regulation Name:	Stereotaxic Instrument
Regulation Number:	21 CFR Section 882.4560
Device Classification:	Class II
Product Code:	OLO

Substantial Equivalence Claimed To:
The subject device, the Mako Total Knee Application, is substantially equivalent to the predicate device, Mako Total Knee Application, cleared via K191998.

In addition, the alignment methods and alignment limits for the subject Mako Total Knee Application are substantially equivalent to those of the reference device, the Triathlon Total Knee System, cleared via K201343.

Device Modification:
The following changes have been made to the Mako Total Knee Application:

- **Indications for Use** – Addition of the Triathlon PSR tibial inserts as compatible for use with the Mako Total Knee Application.
- **Labeling (Mako TKA User Guides)**

- Addition of the Triathlon PSR tibial inserts as compatible for use with the Mako Total Knee Application.
- Addition of an individualized alignment pre-operative planning methodology for Mako Total Knee Application-compatible Triathlon Total Knee System components when placed with the Mako System.

Description:
The Mako System with the subject Mako Total 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 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.

Once configured for a specific application, the Mako robotic-arm can serve as the 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 Device:

The technological characteristics of the Mako Total Knee Application compared to the predicate device are listed below:

Technological Characteristics	Mako Total Knee Application	Mako Total Knee Application – K191998
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
The subject device has the same intended use as that specified in the cleared 510(k) premarket notification for the predicate device listed in this 510(k) premarket notification.

Indications for Use: Mako Total Knee Application

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 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:

- Total Knee Arthroplasty (TKA)

The implant systems compatible with the system:

- Triathlon Total Knee System (CR/CS/PS/PSR cemented and cementless primary)
- Triathlon Total Knee System (TS inserts cemented primary)
- Kinetis Total Knee System (CR/UC)

Performance Data – The modified Mako System with the subject Mako Total Knee Application has been evaluated through the following non-clinical performance testing:

- Simulated-use cadaveric surgeon validation
- Knee alignment clinical outcomes data review

Conclusions:
The hardware and software of the subject Mako System with Mako Total Knee Application is identical to the hardware and software of the predicate Mako System with Mako Total Knee Application. The addition of compatibility with the Triathlon PSR tibial inserts and an individualized alignment pre-operative plan option in the labeling does not impact the intended use or the fundamental technology of the device. Furthermore, performance testing demonstrates that the characteristics of the subject Mako Total Knee Application are equivalent to the characteristics of the predicate device. The subject device is also as safe and as effective as the predicate device and does not raise different questions of safety and effectiveness. Therefore, the performance testing supports a determination of substantial equivalence.