February 25, 2026

Mako Surgical Corp.
Rita Koremblum
Senior Staff Regulatory Affairs Specialist
3365 Enterprise Ave.
Weston, Florida 33331

Re: K260222
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: January 23, 2026
Received: January 26, 2026

Dear Rita Koremblum:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260222

Please provide the device trade name(s).

Mako Total Knee Application

Please provide your Indications for Use below.

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/MS cemented and cementless primary)
• Triathlon Total Knee System (TS inserts, cemented primary)

Please select the types of uses (select one or both, as applicable).

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

K260222

510(k) SUMMARY

Sponsor: Mako Surgical Corp.
3365 Enterprise Ave
Weston, FL 33331

Contact Person: Rita Koremblum
Sr. Staff Regulatory Affairs Specialist
rita.koremblum@stryker.com
201-565-6636

Date Prepared: Jan 23, 2026

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, the Mako Total Knee Application, cleared in K250608.

Device Modifications:

New Implant compatibility: Addition of the Triathlon® X3® Medial Stabilized Tibial Bearing Insert (K253637) to the list of compatible implants with Mako Total Knee Application.

Labeling: Labeling provided with the Mako Total Knee Application has been updated to reflect the proposed modification.

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 camera, a computer, dedicated instrumentation, an operating software, 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 – K250608
Major Components	Robotic arm, Stryker Q Guidance System, cutting system.	Robotic arm, Stryker Q Guidance System, cutting system.
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 total 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/MS cemented and cementless primary)
- Triathlon Total Knee System (TS inserts cemented primary)

Performance Data – Risk analysis, usability and design validation assessments were performed to evaluate the compatibility change and confirmed that no new hazards were introduced and no additional testing or design control activities were required.

Conclusions:
The subject Mako Total Knee Application has the same intended use and fundamental scientific technology as the predicate device. The modification updates the indications for use to add compatibility with the Triathlon® X3® Medial Stabilized Tibial Bearing Insert (K253637) and does not alter the device's design, materials, or principles of operation or raise new or different questions of safety or effectiveness. Comparative design assessments and risk analysis conducted under design controls in accordance with 21 CFR 820 demonstrated that the modification introduces no new hazards and does not impact device performance or clinical use. Therefore, the design control activities conducted by Mako Surgical Corp. support a determination of substantial equivalence for the subject device under the Special 510(k) pathway.