



March 5, 2025

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

Re: K243751

Trade/Device Name: Mako Total Hip Application 5.0
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 4, 2024
Received: December 5, 2024

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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

510(k) Number (if known)

K243751

Device Name

Mako Total Hip Application 5.0

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 total hip arthroplasty 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;

including revision total hip arthroplasty procedures where:

- the primary acetabular component is well-fixed to the pelvic anatomy, and
- the acetabular component can be revised with either a cup or cup and wedge augment construct.

These procedures include: 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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K243751 510(k) SUMMARY

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

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

Date Prepared:

Proprietary Name: Mako Total Hip Application

Common Name: Total Hip Application (THA)

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 Hip Application, is substantially equivalent to the predicate device, Mako Total Hip Application, cleared via K193128.

Device Modifications:

The following changes have been made to the Mako Total Hip Application:

Indications For Use: A revision indication has been added to the Mako Total Hip Application Indications for Use statement.

Integration with the updated Mako 4 Hardware: The subject Mako Total Hip software application has been integrated with the new Mako 4 hardware platform, recently cleared in K241011.

Clinical Software Application:

- New implant system compatibility for revision indication

- Screw planning and intraoperative screw trajectory
- Augment planning, preparation and plane capture
- Additional cup, augment and stem planning features
- Pelvic registration for revision indication
- Bone mapping
- Pre-impaction and post-impaction clocking

Additional Software Changes:

- Update to robotic arm software **CRISIS** to enable compatibility with the updated Mako 4 hardware operating system (Flex OS).
- **MGo:** Minor updates to MGo were required for compatibility with the Flex OS.
- **Treatment Design Application (TDA):** A newer version (1.10) of TDA has been released that supports segmentation of Total Hip Application (THA) revision cases in TDA. Specifically, for revision cases, primary implant surfaces can be segmented in addition to the pelvis, operative femur, and non-operative femur.

Description:

The Mako System with the subject Mako Total Hip Application is a stereotactic instrument that includes a robotic arm, an integrated cutting system, an optical detector, camera, 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 Hip Application compared to the predicate device are listed below:

Technological Characteristics	Mako Total Hip Application	Mako Total Hip Application – K193128
Major Components	Stryker Q-Guidance System, robotic arm, cutting system, preoperative planning laptop	Robotic Arm, Guidance Module, 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 Hip 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 total hip arthroplasty 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;
- including revision total hip arthroplasty procedures where:
- the primary acetabular component is well-fixed to the pelvic anatomy, and
 - the acetabular component can be revised with either a cup or cup and wedge augment construct.

These procedures include: Total Hip Arthroplasty (THA)

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

- Software testing
- Bone registration accuracy verification
- Bone resection accuracy verification
- System verification
- Simulated-Use Cadaveric Surgeon Validation

Conclusions:

The hardware and software of the subject Mako System with Mako Total Hip Application is similar to the hardware and software of the predicate Mako System with Mako Total Hip Application. The software modifications being made do not impact the intended use or the fundamental technology of the device. Furthermore, performance testing demonstrates that the characteristics of the subject Mako Total Hip 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.