MAKO Surgical Corp.  
Karen Ariemma  
Senior Manager Regulatory Affairs  
2555 Davie Road  
Fort Lauderdale, Florida 33317

Re: K172219  
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 21, 2017  
Received: July 24, 2017

Dear Karen Ariemma:

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
510(k) SUMMARY

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

Contact Person: Karen Ariemma
karen.ariemma@stryker.com
Phone: 201-831-5718

Date Prepared: July 21, 2017

Proprietary Name: Mako Total Knee Application

Common Name: Total Knee Application (TKA)

Regulation Name: Stereotaxic Instrument

Regulation Number: 21 CFR 882.4560

Device Classification: Class II

Product Code: OLO

Substantial Equivalence Claimed To:
The Mako Total Knee Application is substantially equivalent to the Mako Total Knee Application cleared via K170581.

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

- Compatible implants - Addition of the Triathlon cementless components (CR and PS femoral components, tibial baseplates and patellar components), Triathlon All Poly tibial components and Triathlon TS inserts.

- Labeling - Implant compatibility has been modified in the Indications for Use.

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

<table>
<thead>
<tr>
<th>Technological Characteristics</th>
<th>Mako Total Knee Application</th>
<th>Mako Total Knee Application (K170581)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Components</td>
<td>Guidance Module, robotic arm, camera stand, cutting system, preoperative planning laptop.</td>
<td>Guidance Module, robotic arm, camera stand, cutting system, preoperative planning laptop.</td>
</tr>
<tr>
<td>Tools/accessories</td>
<td>Various reusable and disposable instruments</td>
<td>Various reusable and disposable instruments</td>
</tr>
<tr>
<td>Image Use</td>
<td>CT</td>
<td>CT</td>
</tr>
</tbody>
</table>

**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 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 cemented and cementless primary)
- Triathlon Total Knee System (TS inserts cemented primary)
- Kinetis Total Knee System (CR/UC)
**Performance Data** - The Mako System has been evaluated through the following non-clinical performance testing:

- Cutting Accuracy Verification
- Full system Cadaver Validation

**Conclusions of Performance Testing:**
Performance testing has demonstrated that the characteristics of the Mako Total Knee 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.