



Food and Drug Administration  
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MA Surgical Corporation  
Jonathan Reeves  
Principal Senior Regulatory Specialist  
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August 6, 2015

Re: K143752  
Trade/Device Name: Total Knee Application (TKA)  
Regulation Number: 21 CFR 882.4560  
Regulation Name: Stereotaxic Instrument  
Regulatory Class: Class II  
Product Code: OLO  
Dated: July 1, 2015  
Received: July 7, 2015

Dear Jonathan Reeves,

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 yours,

**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**

510(k) Number (if known)  
K143572

Device Name  
Total Knee Application (TKA)

Indications for Use (Describe)

Indications for Use:

The Robotic Arm Interactive Orthopedic System (RIO®) is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The RIO® 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 Implants systems with which the system is compatible:

- Kinetic Total Knee System ( CR/UC)
- Triathlon Total Knee System ( CR/CS/PS cemented Primary)

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.**

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## 510(K) SUMMARY

**Submitter:** MAKO Surgical Corp.  
**Address:** 2555 Davie Road, Fort Lauderdale, FL 33317  
**Phone number:** 954-628-0655  
**Fax number:** 954-927-0446  
**Contact Person:** Jonathan Reeves  
**Date Prepared:** December 30, 2014  
**Device Trade 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:

Total Knee Application is substantially equivalent to MAKO Surgical Corp.'s (Robotic Arm Interactive Orthopedic System) RIO® – (Partial Knee Application) PKA cleared via K112507.

### Description:

The Robotic Arm Interactive Orthopedic System (RIO) with Total Knee Arthroplasty 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. RIO uses patient CT data to assist the physician with pre-surgical implant placement planning and intraoperative tracking of the patient's femur and tibia. RIO's robotic arm serves as an "intelligent" tool holder or tool guide used by a surgeon for stereotactic guidance during orthopedic surgical procedures.

The main RIO platform includes an optical detector, computer, dedicated instrumentation, operating software, tools and accessories, cutting system, and a robotic arm. The system's architecture is designed to support total knee 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 and interpretive/intraoperative navigation.

RIO's 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 Total Knee Application compared to the predicate device are listed below:

Technological Characteristics	Total Knee Application	RIO-PKA (K112507)
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
Images Use	CT	CT

### Intended Use/Indications for Use:

The Robotic Arm Interactive Orthopedic System (RIO<sup>®</sup>) is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The RIO<sup>®</sup> 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 with which the system is compatible:

- Kinetis Total Knee System ( CR/UC)
- Triathlon Total Knee System ( CR/CS/PS cemented Primary)

### Performance Data:

Validation / Verification Method	Purpose	Validation / Verification Results
Full System Run-Through Test	Verify that the integration of the Robotic Arm Interactive Orthopedic System (RIO), with the Total Knee Application Software, and supporting instrumentation provides adequate functionality to be able to successfully complete a MAKOplasty Total Knee Arthroplasty procedure	Pass
System Accuracy Test	Verify the overall system accuracy by combining bone registration and bone	Pass

	resection accuracy.	
Bone Registration Accuracy Test	Verify the accuracy of bone registration for the TKA 1.0 Application satisfies the specified requirements.	Pass
RIO 3.0 System Platform Cutting Accuracy Test	Verify the RIO resection accuracy for the Total Knee Arthroplasty Application satisfies the specified requirements.	Pass
TKA Perimeter Retention Accuracy Verification	Verify the RIO perimeter retention accuracy for the Total Knee Arthroplasty Application satisfies the specified requirements.	Pass
TKA Validation	Verify in a simulated-use environment that the integration of the Robotic Arm Interactive Orthopedic System (RIO) with the Total Knee Application Software and supporting instrumentation provides adequate functionality to successfully complete a MAKOplasty Total Knee Arthroplasty procedure and satisfies the customer requirements.	Pass

**Clinical Data:**

The Robotic Arm Interactive Orthopedic System (RIO) Total Knee Arthroplasty (TKA) study was a prospective, non-randomized, multi-center study conducted at three sites in the US. The purpose of the RIO TKA IDE study was to demonstrate safety and effectiveness of the RIO system in total knee arthroplasty at 3 months. A total of 100 subjects were consented and enrolled. A total of 89 subjects were implanted using the RIO System and all have successfully completed pre-operative, intra-operative, and 3 month post-operative visits.

There were 49 female (55.1%) subjects and 40 (44.9%) male subjects. Refer to table below for age, height and weight distribution for this population

Label	N	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	Minimum	Maximum
Age	89	65.78	8.49	65.00	60.00	72.00	45.00	83.00
Height (in)	89	67.34	3.84	67.00	65.00	70.00	60.00	75.00
Weight (lb)	89	202.61	38.96	197.00	175.00	226.00	122.00	318.00
BMI	89	31.43	5.70	31.07	27.45	33.78	21.61	52.90

The primary study endpoint was to demonstrate the safety of the RIO Total Knee Arthroplasty Application based on surgeon assessment of complications intra-operatively and at a short term follow up. The safety analysis focused on the complications identified by the Knee Society TKA Complications Workgroup in 2012 for total knee arthroplasty. A review of the literature was performed to identify currently published occurrence rates in manually instrumented TKA for each standardized TKA complication. The analysis of the safety profile was designed to provide clinical data necessary to test the hypothesis that there is no clinically significant increase in the incidence of selected device-related adverse events when using the investigational device relative to manual TKA. No subject experienced any of the rare adverse events that comprise the primary composite safety events (0/89). Therefore, the study meets its primary safety study success criterion.

The secondary endpoint was post-operative radiographic limb alignment of the operative knee assessed at the 3 month post-operative by two independent reviewers. The measured post-operative limb alignment was compared to the derived subject-specific value for the intended limb alignment established prior to bone resection. Two subjects were excluded from the assessment due to issues with the methods of collecting the images used to make the assessment. Excluding these two subjects, independent surgeon reviewer one measured an estimated mean limb alignment deviation from plan of  $1.53^\circ (\pm 1.05^\circ)$  and independent surgeon reviewer two measured an estimated mean limb alignment deviation from plan of  $1.56^\circ (\pm 1.04^\circ)$ .

In addition to reporting accuracy in achieving post-operative limb alignment, malalignment was defined as a radiographically determined alignment angular deformity in the coronal plane greater than  $10^\circ$  from the mechanical axis. Alignment was assessed in descriptive analysis as a categorical variable using the categories appearing in the Knee Society Score, Doctor Portion. These categories are  $0-4^\circ$ ,  $5-10^\circ$ ,  $11-15^\circ$ , and Other, however, these ranges do not account for the surgeon's subject-specific intended post-operative limb alignment. Forty (40) of 89 subjects (44.9%) reported post-operative KSS limb alignment of  $0-4^\circ$ , which is associated with a 3-point deduction in KSS score per degree, while 49/89 (55.1%) reported KSS limb alignment of  $5-10^\circ$  which received no deduction according to the Knee Society Score. No subject reported malalignment as defined above.

The supporting study endpoint was to demonstrate improvement in post-operative subject function at the three month interval as compared to the subject's pre-operative function as measured by the WOMAC. In order to meet the study success criterion, a reduction in the WOMAC score from pre-op to 3 months was necessary. Subjects exhibited a mean 29.6 points reduction, indicating improvement over pre-operative score.

There were 33 reported Adverse Events (AEs) occurring in 32 of the study subjects. Study investigators classified relatedness of all AEs as definitely related, possibly related, or not related to the study system or procedure. There was 1 (1/33, 3.0%) AE that was considered related to the system or procedure. The AE was for an Unanticipated Adverse Device Effect (UADE) for retained foreign body (saw tooth). There were 3 (3/33, 9.1%) that were considered possibly related to the device. The SAEs possibly related to the device included: UADEs was for retained foreign body (saw tooth) (1) and swelling and pain (2). There were a total of 9 (9/33, 27.2%) reported serious AEs (SAEs) that were not related to the device or procedure. These included (8) manipulation under anesthesia (MUA) and (1) pulmonary embolism.

A second surgery was required for two subjects to remove a retained foreign body. For one of the subjects, a revision of the tibial insert was required to locate the foreign body and irrigate the joint space.

The safety and effectiveness of the Robot Arm Interactive Orthopaedic System (RIO®) used for Total Knee Replacement (TKR) has been demonstrated. No subject experienced any rare adverse events that comprised the composite safety events. Secondary endpoints of postoperative limb alignment and clinical outcomes scores at three months postoperatively demonstrated non-inferiority to TKR used with manual instruments as reported in the literature.

**Conclusions of Clinical and Non-Clinical Data:**

The results of the clinical and non-clinical data indicate the device performed within the intended use and did not raise any new safety and efficacy issues. The device was found to be substantially equivalent to the predicate device.

