DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 20, 2015

MAKO Surgical Corporation
Mr. Jonathan Reeves
Senior Regulatory Affairs Specialist
2555 Davie Road
Fort Lauderdale, Florida 33317

Re: K143635
Trade/Device Name: The KINETIS™ Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, OIY
Dated: December 19, 2014
Received: December 24, 2014

Dear Mr. 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" (21CFR 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,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K143635

Device Name: The KINETIS™ Total Knee System

Indications for Use:

The KINETIS™ Total Knee System components are indicated for use in skeletally mature patients, with severe knee pain and disability, undergoing primary surgery for total knee replacement due to:

- Rheumatoid arthritis, osteoarthritic, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle
- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis
- Moderate valgus, varus, or flexion deformities.

MAKO KINETIS™ Total Knee Replacement System components are indicated for use only with cement and are single use devices

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(K) SUMMARY

Submitter:	MAKO Surgical Corp.
Address:	2555 Davie Road, Fort Lauderdale, FL 33317
Phone number/ Fax Number:	(Ph) 954-628-0665; (F) 954-927-0446
Contact Person:	Jonathan Reeves
Date Prepared:	December 19, 2014
Proprietary Name:	The Kinetis™ Total Knee System
Common Name:	Total Knee System
Classification:	Class II
Product Codes/Classification#:	JWH - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (888.3560) OIY - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (888.3560)
Reason for 510(k) submission:	New device submission

Device Description:
The Kinetis™ Total Knee System is a patellofemorotibial polymer/metal/polymer semi-constrained cemented knee joint prosthesis. The system includes femoral component, tibial tray, biomimetic tibial inserts, patella component, and associated instruments. The biomimetic tibial inserts are manufactured from highly cross-linked vitamin E polyethylene. The system is for use in cases where the anterior and posterior cruciate ligaments are retained.

Intended Use:
The Kinetis™ Total Knee System components are indicated for use in skeletally mature patients, with severe knee pain and disability, undergoing primary surgery for total knee replacement due to:

- Rheumatoid arthritis, osteoarthritic, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle
- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis
- Moderate valgus, varus, or flexion deformities.

MAKO Kinetis™ Total Knee System components are indicated for use only with cement and are single use devices.

Primary Predicate Device:
MAKO Kinetis™ Total Knee System is substantially equivalent to the following 510(k) cleared device:

Device Name	Manufacturer	510(k) #
Vanguard XP Knee System	Biomet	K122160

Additional Predicate Devices:

Device Name	Manufacturer	510(k) #
Townley Total Knee	BioPro	K904448
Axiom Knee	Orthomet	K926334

References Devices:

Device Name	Manufacturer	510(k) #
Total Knee System	Pipeline	K123692

Technological Characteristics:
The Kinetis™ Total Knee System is similar to legally marketed devices listed previously in that they share the same indications for use, are manufactured from the same or similar material, have same or similar design/technological characteristics, and have performance characteristics adequate to withstand anticipated physiological loading.

Performance Data:
The Kinetis™ Total Knee System has been evaluated through non-clinical performance testing for;

- Tibial Baseplate Fatigue
- Tibial Baseplate Fixation
- Insert Locking Mechanism Strength
- Tibial Insert / Baseplate Micromotion
- Tibio-Femoral Range of Motion
- Tibio-Femoral Range of Constraint
- Tibio-Femoral Contact Area and Stress
- Tibial Insert Fatigue
- Patello Femoral Subluxation
- Patello-Femoral Lateral Jump Height
- Patello-Femoral Contact Area and Stress
- Femoral Fatigue
- Wear

- Tibial Eminence Strength

Conclusions from Clinical and Non-clinical Data:
The results of performance testing indicated 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 devices.