Restoris® Porous Partial Knee System
510(k) Summary

JUL 0 8 2014

Device Proprietary Name:	Restoris Porous Partial Knee System
Common Name:	Artificial Partial Knee System
Classification regulation:	888.3530 (Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis) and 888.3535 (Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis)
Device Class:	Class II
Product Codes:	HRY and NJD
Submitter's Name:	MAKO Surgical Corp.
Address:	2555 Davie Road Fort Lauderdale, FL 33317
Contact Person:	Robert C. Cohen
Telephone Number:	(973) 267-8800
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Date Summary Prepared:	December 13, 2013

Device Description:

The Restoris® Porous Partial Knee System is a unicompartmental knee system that includes porous coated, cast CoCr, asymmetric femoral components in sizes 1 – 8; and Ti6Al4V, asymmetric, porous tibial baseplate components in sizes 1 – 8. The subject femoral and tibial baseplate components are compatible and are intended for use with predicate MAKO Restoris MCK Tibial Onlay Inserts in standard UHMWPE or highly crosslinked vitamin E UHMWPE (K090763, K133039). The sagittal articular surface of the femoral condyle has an extended posterior radius that accommodates flexion up to 155°.

Intended Use

The Restoris® Porous Partial Knee System components are intended for unicompartmental knee arthroplasty to treat one or more of the following conditions:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis.
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of an unicompartmental knee prosthesis.

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- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

The Restoris® Porous Femoral Component and PST® Tibial Baseplate are intended for cementless or cemented fixation. The Tibial Baseplate may be used in conjunction with ancillary screw fixation. The porous surfaces of both the femoral and tibial tray components provide biological fixation when used in a cementless application.

Predicate Devices:
Restoris® Porous Partial Knee System is similar to the following predicates:

Trade/Proprietary Name	Manufacturer	510(K) #	Clearance Date
Restoris MCK Knee System	MAKO Surgical	K090763	6/17/2009
MMCK Uni Knee System	MAKO Surgical	K082172	11/28/2008
Natural-Knee® II Unicompartmental Knee System	CenterPulse Orthopedics/Zimmer	K033810	3/5/2004
MAKO Restoris® Hip System (Pipeline Total Hip System)	MAKO (Pipeline Orthopedics acquired by MAKO)	K112802	03/12/2012

Purpose of Submission:
The 510(k) submission is for new unicompartmental knee system femoral and tibial tray components.

Technological Characteristics:
The Restoris® Porous Partial Knee System has the same indications for use, design features, and materials as one or more of the identified predicate knee systems. The porous surface of the subject Restoris® Porous Partial Knee System tibial baseplates is the same as the porous surface of the predicate MAKO Restoris® Total Hip System (K112802) acetabular shells.

Performance Testing:
The Restoris® Porous Partial Knee System has been evaluated, either by new testing and analysis submitted in this 510(k) for femoral component fatigue, tibial baseplate fatigue, and porous surface characterization, or by testing previously submitted in predicate 510(k) #K090763 or #K133039 for the tibial insert/baseplate locking mechanism strength, femorotibial conguency, femorotibial contact area, and range of motion. The testing demonstrates that the Restoris® Porous Partial Knee System when used as intended with the predicate MAKO Restoris MCK Tibial Onlay Inserts, is capable of withstanding expected in vivo loading and is substantially equivalent to predicate knee systems.

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Conclusions:

The Restoris® Porous Partial Knee System has the same indications for use, is manufactured from the same materials, and has similar design features as compared with one or more of the predicate knee systems. Characterization of the device porous surfaces has shown them equivalent to predicate device porous coatings. Engineering analyses and mechanical testing demonstrate that the performance characteristics of the Restoris® Porous Partial Knee System are equivalent to those of other legally marketed knee systems. Therefore, the Substantial Equivalence of the subject device for the proposed indications for use is demonstrated.

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

July 8, 2014

MAKO Surgical Corp.
% Ms. Terry Sheridan Powell
Consultant
M Squared Associates, Inc.
575 Eighth Avenue
Suite 1212
New York, New York 10018

Re: K133811
Trade/Device Name: Restoris Porous Partial Knee System
Regulation Number: 21 CFR 888.3535
Regulation Name: Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis
Class: Class II
Product Code: NJD, HRY
Dated: May 23, 2014
Received: May 27, 2014

Dear Ms. Powell:

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,

Lori A. Wiggins

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

Enclosure

Indications for Use Statement

510(k) Number: ~~To be assigned~~ K133811

Device Name: Restoris® Porous Partial Knee System

Indications for Use:

The Restoris® Porous Partial Knee System components are intended for unicompartmental knee arthroplasty to treat one or more of the following conditions:

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- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of a unicompartmental knee prosthesis.
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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

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