K090763 #1/2

JUN 17 2009

2555 Davie Road • Ft. Lauderdale, FL 33317 • Phone 954.927.2044 • Fax 954.927.0446 • www.makosurgical.com

510(K) SUMMARY

Submitter:	MAKO Surgical Corp.
Address:	2555 Davie Road, Fort Lauderdale, FL 33317
Phone number / Fax Number:	(Ph) 954-927-2044 x 605; (F) 954-927-0446
Contact Person:	William F. Tapia
Date Prepared:	March 18, 2009
Proprietary Name:	Restoris MultiCompartmental Knee System (Restoris MCK)
Common Name:	Compartmental Knee Prosthesis System
Classification:	Class II
Product Code / #:	KRR – Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis; 21 CFR 888.3540 HSX – Knee joint femorotibial metal/polymer non-constrained cemented prosthesis; 21 CFR 888.3520 NPJ - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis; 21 CFR 888.3560 HRY - Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis; 21 CFR 888.3530

Description: The Restoris MCK is composed of a unicompartmental implant system (Restoris MCK Uni) and a patellofemoral implant system (Restoris MCK PF). Restoris MCK Uni and Restoris MCK PF may be used in various combinations to create: a single unicompartmental femorotibial replacement for the medial or lateral side of the knee; a patellofemoral replacement; or a bicompartmental patellofemorotibial replacement for the medial side of the knee. Restoris MCK Uni is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.

Feature	Restoris MCK
Implant Components	o Restoris MCK Uni - Femoral Condyle component - Tibial Inlay component - Radiographic marker in Tibial Inlay component - Tibial Onlay Insert component - Tibial Baseplate o Restoris MCK PF - Patellofemoral component - Patella component
Sizes	o Restoris MCK Uni - Femoral Condyle components are available in 8 sizes. - Tibial components are available in 8 sizes. o Restoris MCK PF - Patellofemoral components available in 8 sizes. - Patella components are available in 6 sizes.
Materials	o Restoris MCK Uni - Femoral Condyle component – CoCrMo alloy - Tibia Inlay component – UHMWPE - Radiographic marker in Tibial Inlay component – Unalloyed titanium wire - Tibia Onlay Insert component – UHMWPE - Tibial Baseplate – Ti6Al4V ELI alloy o Restoris MCK PF - Patellofemoral component – CoCrMo alloy - Patella component – UHMWPE
Instrumentation	Provided separately in a re-usable/sterilizable tray. Tray includes various tools (e.g., sizers, templates, trials, drills, gauges, impactors, inserters, extractors) used during surgery. Restoris MCK can only be used with the MAKO Robotic Arm Interactive Orthopedic System (RIO).

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Sterilization and Packaging	Sterilization: o All components – gamma radiation o Instrumentation – steam sterilization Packaging: o All components are supplied in double sealed containers maintaining double sterile barriers.
Biocompatibility	All components are made of materials for surgical implant applications per recognized ASTM standards.

Substantial Equivalence: Restoris MCK is substantially equivalent to the MAKO Modular Knee Compartmental Knee System (K082172).

Indications for Use:

RESTORIS MCK is indicated for single or multi-compartmental knee replacement used in conjunction with RIO, the Robotic Arm Interactive Orthopedic System, in individuals with osteoarthritis or post-traumatic arthritis of the tibiofemoral and/or patellofemoral articular surfaces. The specific knee replacement configurations include:

- Medial unicondylar
- Lateral unicondylar
- Patellofemoral
- Medial bi-compartmental (medial unicondylar and patellofemoral)

RESTORIS MCK is for single use only and is intended for implantation with bone cement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2009

MAKO Surgical Corporation
% Mr. William F. Tapia
2555 Davie Road
Fort Lauderdale, Florida 33317

Re: K090763
Trade/Device Name: Restoris MultiCompartmental Knee System (Restoris MCK)
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: NPJ, KRR, HSX, HRY
Dated: March 17, 2009
Received: March 23, 2009

Dear Mr. Tapia:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known): K090763

Device Name: Restoris MultiCompartmental Knee System (Restoris MCK)

Indications for Use:

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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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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