K082172 #1/2

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

NOV 28 2008

ATTACHMENT 3 - 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:	July 30, 2008
Proprietary Name:	MAKO Surgical Corp. Compartmental Knee Implant System (MMKC)
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 MMKC is composed of a unicompartmental implant system (MMKC-Uni) and a PF implant system (MMKC-PF). MMKC-Uni and MMKC-PF may be used in various combinations to create: a single unicompartmental femorotibial replacement for the medial side of the knee; a patellofemoral replacement; or a bicompartmental patellofemorotibial replacement for the medial side of the knee. MMKC-UNI is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.

Feature	MAKO Surgical Corp. Compartmental Knee Implant System (MMKC)
Implant Components	o MMKC-Uni - Femoral component - Tibial inlay component - Radiographic marker in tibial inlay component - Tibial onlay insert component - Tibial baseplate o MMKC-PF - Patellofemoral component - Patella component
Sizes	o MMKC-Uni - Femoral components are available in 8 sizes. - Tibial components are available in 8 sizes. o MMKC-PF - Patellofemoral components available in 8 sizes. - The patella components are available in 6 sizes.
Materials	o MMKC-Uni - Femoral component – CoCr - Tibia Inlay component – UHMWPE - Radiographic marker in tibial inlay component– Titanium wire - Tibia onlay insert component – UHMWPE - Tibial Baseplate – Ti6Al4V o MMKC-PF - Patellofemoral component – CoCr - Patella component – UHMWPE
Instrumentation	Provided separately in a re-usable/sterilizable tray. Tray includes various tools (e.g., sizers, templates, trials, drill, gage, impactors, inserters, extractors) used during surgery. MMKC, MMKC-Uni, MMKC-PF can only be used with the MAKO Tactile Guidance System (TGS).

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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: The MAKO Surgical Corp. Compartmental Knee Implant System is substantially equivalent to MAKO Surgical Corp.'s Patellofemoral Knee Implant System (K080029); MAKO Surgical Corp.'s Unicondylar Knee Implant System II (K080368); Stryker® Compartmental Knee System (K052917); Depuy Graduated Compartmental Knee (K061648) and DePuy GCK Femoral and Tibial Components (K070849)

Indications for Use:

The MAKO Modular Knee Compartmental Implant System is indicated for single or multi-compartmental knee replacement used in conjunction with the MAKO Tactile Guidance System in individuals with osteoarthritis or post traumatic arthritis of the medial tibiofemoral and/or patellofemoral articular surfaces.

The MAKO Modular Knee Compartmental Implant System 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

NOV 2 8 2008

MAKO Surgical Corp.
% Mr. William F. Tapia
Vice President, Regulatory
2555 Davie Road
Fort Lauderdale, Florida 33317

Re: K082172
Trade/Device Name: MAKO Modular Knee Compartmental Implant System (MMKC)
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: NPJ, KRR, IISX, HRY
Dated: November 18, 2008
Received: November 19, 2008

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

MAKO SURGICAL CORP®

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ATTACHMENT 2

INDICATIONS FOR USE

510(k) Number (if known): K082172

Device Name: MAKO Modular Knee Compartmental Implant System (MMKC)

Indications for Use:

The MAKO Modular Knee Compartmental Implant System is indicated for single or multi-compartmental knee replacement used in conjunction with the MAKO Tactile Guidance System in individuals with osteoarthritis or post traumatic arthritis of the medial tibiofemoral and/or patellofemoral articular surfaces.

The MAKO Modular Knee Compartmental Implant System is for single use only and is intended for implantation with bone cement.

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)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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