K082081 #1/2

OCT 15 2008

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

ATTACHMENT 2

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 22, 2008
Proprietary Name:	MAKO Surgical Corp. Unicondylar Knee Implant System III
Common Name:	Unicondylar Knee System
Classification Name / #:	Class II; 21 CFR 888.3520
Product Code:	87 HSX – Knee Joint Femorotibial, Metal/Polymer Non-Constrained, Cemented Prosthesis

Substantial Equivalence: The MAKO Surgical Corp. Unicondylar Knee Implant System III is substantially equivalent to the Encore EPIK® Uni Knee System (K020741 & K022437), MAKO Surgical Corp. Unicondylar Knee Implant System II (K080368), and the Zimmer Unicompartmental Knee System (ZUK - K033363)

Feature	MAKO Surgical Corp. Unicondylar Knee Implant System III (MUKSIII)
Implant Components	o Femoral component o Tibial inlay component o Radiographic marker in tibial inlay component o Tibial onlay insert component o Tibial baseplate
Sizes	o Femoral components are available in 8 sizes. o Tibial components are available in 8 sizes
Materials	o Femoral component – CoCrMo o Tibia Inlay component – UHMWPE o Radiographic marker in tibial inlay component– Titanium wire o Tibia onlay insert component – UHMWPE o Tibial Baseplate - Titanium
Instrumentation	Provided separately in a re-usable/sterilizable tray. Tray includes various tools (e.g., femoral trials, tibial insert and baseplate trials, impactors, inserters, extractors) used during surgery. MUKSIII can also be used with MAKO Tactile Guidance System (TGS).
Sterilization and Packaging	Sterilization: o Femoral and tibial components – gamma radiation o Instrumentation – steam sterilization Packaging: o Both femoral and tibial components are supplied in double sealed containers maintaining double sterile barriers.
Biocompatibility	Both devices are made of materials for surgical implant applications per recognized ASTM standards.

Description: This device consists of a CoCrMo femoral condyle component, a titanium alloy baseplate, and ultra-high molecular weight polyethylene tibial onlay and inlay components. These components have been designed to fit the medial and lateral compartments and are intended for cemented, one-time use only. The femoral condyle component features a polished articular surface, a cement pocket, and 2 fixation pegs. The design of the femoral condyle component allows for up to 155° flexion. The tibial components consist of a tibial onlay (tibial baseplate and tibial onlay insert) and a tibial inlay. The tibial onlay components snap together with an interlocking mechanism. The tibial inlay contains a dovetail channel on the bottom side and a peripheral cement channel to enhance fixation when cemented in the tibia.

The MAKO Surgical Corp. Unicondylar Knee Implant System III is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.

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Indications for Use: MAKO Surgical Corp. Unicondylar Knee Implant System III components are for use in unicompartmental knee arthroplasty as a result of:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post-traumatic arthritis
- Revision of previous unsuccessful unicompartmental knee replacement
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis

These components are single use only and are intended for implantation with bone cement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2008

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

Re: K082081
Trade/Device Name: MAKO Surgical Corporation Unicondylar Knee Implant System III
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: July 22, 2008
Received: July 23, 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

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ATTACHMENT 1

INDICATIONS FOR USE

510(k) Number (K082081):

Device Name: MAKO Surgical Corp. Unicondylar Knee Implant System III

Indications for Use:

MAKO Surgical Corp. Unicondylar Knee Implant System III components are for use in unicompartmental knee arthroplasty as a result of:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post-traumatic arthritis
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These components are single use only and are intended for implantation with bone cement.

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

for mxm

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

510(k) Number K082081