



K080029 1/2

MAY 16 2008

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: May 14, 2008
Proprietary Name: MAKO Surgical Corp. Patellofemoral Knee Implant System
Common Name: Patellofemoral replacement, patellofemoral knee system
Classification Name / #: Class II; 21 CFR 888.3540
Product Code: 87 KRR – Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis

Substantial Equivalence: The MAKO Surgical Corp. Patellofemoral Knee Implant System is substantially equivalent to Stryker Corporation's Avon™ Patello-femoral Joint Prosthesis (510k # - K010100); Avon™ Patellar Component (510k # K020841); Avon™ Extra Small Patello-femoral Replacement (510k # K041160) and Avon™ PFJ Prosthesis; (510k # K051948).

| Feature | MAKO Surgical Corp. Patellofemoral Knee Implant System |
|----------------------------------|--|
| Intended Use/Indications for Use | The MAKO Surgical Corp. Patellofemoral Knee Implant System is intended to be used in cemented patello-femoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists. |
| Implant Components | <ul style="list-style-type: none"> o Patellofemoral component – CoCr o Patella component – UHMWPE o Radiographic o-ring in patella component |
| Sizes | <ul style="list-style-type: none"> o Patellofemoral components available in 8 sizes. o The patella components are available in 6 sizes |
| Materials | <ul style="list-style-type: none"> o Patellofemoral component – CoCr o Patella component – UHMWPE o Radiographic o-ring marker – titanium wire |
| 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. |
| Sterilization and Packaging | Sterilization: <ul style="list-style-type: none"> o Patellofemoral and patella components – gamma radiation o Instrumentation – steam sterilization Packaging: <ul style="list-style-type: none"> o Both patellofemoral and patella 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 patellofemoral component and an ultra-high molecular weight polyethylene patella component. These components are intended for cemented, one-time use only. The anterior surface of the patellofemoral component is polished and features a trochlear groove. The posterior surface of the patellofemoral and patella component employ features such as cement pockets and pegs for enhanced stability of the prosthesis when cemented onto the femur and patella, respectively.



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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAKO Surgical Corp.
% William F. Tapia
2555 Davie Road
Suite 110
Ft. Lauderdale, FL 33317

MAY 16 2008

Re: K080029
Trade/Device Name: MAKO Surgical Corp. Patellofemoral Knee Implant System
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee joint patellofemoral polymer/metal
semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRR
Dated: May 14, 2008
Received: May 15, 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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EXHIBIT G

INDICATIONS FOR USE

510(k) Number (if known): K080029

Device Name: MAKO Surgical Corp. Patellofemoral Knee Implant System

Indications for Use:

The MAKO Surgical Corp. Patellofemoral Knee Implant System is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

These components are single use only and are 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)

Neil R. Del Forman
Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K080029