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BIOMET®
ORTHOPEDICS, INC.

510(k) Summary

Preparation Date: July 7, 2008

Applicant/Sponsor: Biomet Manufacturing Corp.
56 East Bell Drive
Warsaw, IN 46582

JUL 29 2008

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Maestro™ Wrist Fracture Implant

Common Name: Total wrist replacement device

Classification Name:
Wrist joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3800)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
- Maestro™ Total Wrist System, 510(k) K042032
- Maestro™ Carpal HemiArthroplasty, 510(k) K050028

Device Description:
The Maestro™ Wrist Fracture Replacement System consists of a two piece radial component and a molded carpal bearing component for total wrist replacement. The radial component is composed of a distal body with a modular stem. The distal bodies have a highly polished bearing surface located anatomically. The Maestro™ Tapered Carpal Component is composed of three subcomponents – a carpal head, a carpal plate and a capitate stem. The carpal head is composed of polyethylene molded on to a metallic base. The carpal plate has a male taper which mates with a female taper in the carpal head. The plate features threaded screw holes that mate with the heads of spherical locking screws. Screws are available with both fixed and variable heads. The variable screws allow the surgeon to angle the screws upon insertion while still locking the screws to the plate. The capitate stem then screws into internal threads on the reverse side of the taper on the carpal plate to complete the implant.

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Office: 574.267.6639
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Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

Intended Use: The Maestro™ Total Wrist System is indicated for use as a replacement of wrist joints disabled by pain, deformity and/or limited motion caused by:

1) Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis and avascular necrosis.
2) Rheumatoid arthritis.
3) Revision where other devices or treatments have failed.
4) Scapholunate Advanced Collapse (SLAC) and other functional deformities.
5) Trauma, including fractures of the distal radius and/or carpal bones.

The radial and carpal components are intended to be implanted with bone cement.

Summary of Technologies: The Maestro™ Wrist Fracture Implant has similar technologies as the predicate device.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Manufacturing Corp.
% Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
56 East Bell Drive
Warsaw, IN 46582

JUL 29 2008

Re: K080426
Trade/Device Name: Maestro Wrist Fracture Implant
Regulation Number: 21 CFR 888.3800
Regulation Name: Wrist joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWJ
Dated: July 21, 2008
Received: July 22, 2008

Dear Ms. Beres:

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

Indications for Use

510(k) Number (if known): K080426

Device Name: Maestro™ Wrist Fracture Implant

Indications For Use: The Maestro™ Total Wrist System is indicated for use as a replacement of wrist joints disabled by pain, deformity and/or limited motion caused by:

1) Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis and avascular necrosis.
2) Rheumatoid arthritis.
3) Revision where other devices or treatments have failed.
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5) Trauma, including fractures of the distal radius and/or carpal bones.

The radial and carpal components are intended to be implanted with bone cement.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___NO___
(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)

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

510(k) Number K080426