K050028

MAR 25 2005

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Maestro™ Carpal HemiArthroplasty

Common Name: Partial Wrist Joint

Classification Name: Prosthesis, Wrist Carpal Lunate (21 CFR 888.3750 and/or Prosthesis, Wrist, Carpal Scaphoid (21 CFR 888.3760)

The Maestro™ Carpal HemiArthroplasty requires removal of both the lunate and the scaphoid bones therefore it does not clearly fit one classification

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Swanson Titanium Carpal Scaphoid Implant (Wright Medical Technologies) - K864490
Swanson Titanium Carpal Lunate Implant (Wright Medical Technologies) - K864491
Maestro™ Total Wrist System (Biomet Manufacturing Corp.) - K042032

Device Description: The Maestro™ Carpal HemiArthroplasty is a three piece carpal component designed to articulate with the natural radial bone. The carpal component consists of 3 sub-components – a carpal head, a carpal plate and a capitate stem. The carpal head comes in 3 heights, standard, +2 and +4. This allows the surgeon to adjust for soft tissue laxity. Two lengths of carpal plates give the surgeon options of screw placement.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639

FAX
574.267.8137

E-MAIL
biomet@biomet.com

Intended Use: The Maestro™ Carpal HemiArthroplasty 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 carpal bones

The device is intended to be implanted with bone cement.

Summary of Technologies: The overall design, materials, surface finishes and processing of the Maestro™ Carpal HemiArthroplasty are similar or identical to the predicate devices.

Non-Clinical Testing: Mechanical testing has demonstrated the device's ability to perform under expected clinical conditions.

Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corporation
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K050028
Trade/Device Name: Maestro™ Carpal HemiArthroplasty
Regulation Numbers: 21 CFR 888.3750, 21 CFR 888.3760
Regulation Names: Wrist joint carpal lunate polymer prosthesis, Wrist joint carpal scaphoid polymer prosthesis
Regulatory Class: II
Product Codes: KWN, KWO
Dated: January 5, 2005
Received: January 6, 2005

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.

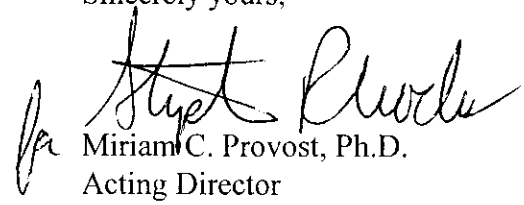
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Miriam C. Provost, Ph.D.
Acting 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): K050028

Device Name: Maestro™ Carpal HemiArthroplasty

Indications For Use: The Maestro™ Carpal HemiArthroplasty 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 carpal bones

The device is intended to be implanted with bone cement.

Prescription Use X AND/OR Over-The-Counter Use
(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

Page 1 of 1

510(k) Number K050028