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FEB - 9 2005

BIOMET

510(k) Summary

Applicant/Sponsor:

Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person:

Gary Baker
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (574) 267-6639
FAX: (574) 372-1683

Proprietary Name: Discovery™ - Mosaic™ Total Humerus System

Common Name: Shoulder Prosthesis

Classification Name: Prosthesis, Shoulder, Non-Constrained, Metal/Polymer, Cemented (21 CFR §888.3650)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Discovery™ Elbow – Mosaic™ Distal Humeral Replacement System: K033280 – Biomet Inc.
3 Piece Proximal Humeral Replacement System: K020045 - Biomet Inc.

Device Description:

The Discovery™ - Mosaic™ Total Humerus System includes the components of the Discovery Elbow, the components of the 3 Piece Proximal Humeral Replacement System, and an intercalary segment designed to connect them. The Discovery™ - Mosaic™ Total Humerus System uses the same modular heads and glenoid components that were cleared for use in the predicate 3 Piece Proximal Humeral Replacement System.

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

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Intended Use:

The indications for use for the Discovery™ – Mosaic™ Total Humerus System include:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2. Rheumatoid arthritis
3. Revision where other devices or treatments have failed
4. Correction of functional deformity
5. Treatment of acute or chronic fractures with humeral epicondyle (elbow) involvement or humeral head (shoulder), which are unmanageable using other treatment methods
6. Oncology applications

The Discovery™ - Mosaic™ Total Humerus System is intended for cemented use only.

Summary of Technologies:

The Discovery™ - Mosaic™ Total Humerus System components have the same intended use, the same functional characteristics, and are manufactured from the same materials as the predicate devices.

Non-Clinical Testing:

The performance data indicated that the Discovery™ - Mosaic™ Total Humerus System is substantially equivalent to the predicate devices for the uses indicated.

Clinical Testing:

Clinical testing was not required for these components to support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 2005

Gary Baker
Regulatory Specialist
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581

Re: K043505
Trade/Device Name: Discovery™ – Mosaic™ Total Humerus System
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWT
Dated: December 17, 2004
Received: December 20, 2004

Dear Mr. Baker:

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.

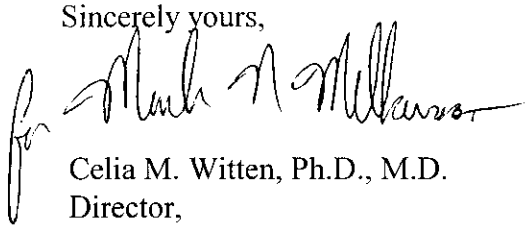
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0210. 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,



Celia M. Witten, Ph.D., M.D.
Director,
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications For Use

510(k) Number (IF KNOWN): K043505

Device Name: Discovery™ - Mosaic™ Total Humerus System

Indications for Use:
The indications for use for the Discovery™ – Mosaic™ Total Humerus System include:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2. Rheumatoid arthritis
3. Revision where other devices or treatments have failed
4. Correction of functional deformity
5. Treatment of acute or chronic fractures with humeral epicondyle (elbow) involvement or humeral head (shoulder), which are unmanageable using other treatment methods
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The Discovery™ - Mosaic™ Total Humerus System is intended for cemented use only.

Prescription Use __X__ **OR** **Over-the-Counter Use**_____
(Per 21 CFR 801 Subpart D) (Per 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 K043505