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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

The following 510(k) Summary of Safety and Effectiveness information is provided in accordance with the requirements of 21 CFR 807.92 and SMDA 1990.

510(k) Number: K043346

Date: January 26, 2005

Applicant: Genesis Medical LLC

Address: 2650 US Highway 130, Cranbury, NJ 08512

Contact Person: Perry Geremakis

Phone number: 609 409-3316

Fax number: 609 409 3317

Trade Name: Genesis Total Shoulder Replacement

Common Name: Shoulder prosthesis

Classification Name: Prosthesis, shoulder, semiconstrained, metal/polymer, cemented

Device Description: The humeral stem is manufactured from titanium 6-Al-4V alloy and has a corundum blasted surface to enhance bone cement fixation. Lateral fins with suture holes are designed for soft tissue attachment. There is a 6 degree male taper to mate with humeral heads. The devices features an anatomical neck/shaft angle. The humeral head is fabricated from cobalt chromium alloy. The head has a low profile and manufactured with a 6 degree taper to mate with the humeral stem. There are numerous head diameters to accommodate anatomical patient variations. An offset head at 4 mm is also available to permit soft tissue balancing and to enhance joint stability. The glenoid component is fabricated from ultra-high molecular-weight polyethylene. It is designed with a pear shaped frontal profile for anatomical fit to the glenoid which avoids soft tissue impingement. The articular surface radius of curvature is oversized to the humeral heads to accommodate multiple humeral head sizes. The device is designed with 3 peg fixation. The pegs are co-linear to help avoid punch through of thin cortical walls at the outer edges of the glenoid. The undersurface is keeled to enhance bone cement fixation.

Intended Use: The device is intended for cemented use for a severely painful and/or disabled shoulder joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis. It is also intended for fracture dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory. The device can be used in other difficult clinical problems where shoulder arthrodesis or resection arthroplasy are not acceptable (e.g., revision a failed primary component). Hemi-shoulder replacement is also indicated for un-united humeral head fractures and avascular necrosis of the humeral head.

Predicate Devices: Substantial equivalence is derived from a composite of characteristics from multiple predicate devices including the Zimmer Select, the Biomet Bio-Modular total shoulder, Tornier Aequalis, the Global Total Shoulder and the Solar shoulder system.

Technological Characteristics: The Genesis Total Shoulder replacement has similar intended use, design intent, dimensions, surgical technique, materials, biocompatibility and labeling as that of predicate devices. Any noted differences do not raise new types of safety and effectiveness questions, nor are there new technological issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 1 2005

Mr. Perry A. Geremakis
President, Chief Executive Officer
Genesis Medical L.L.C
32 Iron Horse Rd
Oakland, New Jersey 07436

Re: K043346
Trade/Device Name: Genesis Total Shoulder Replacement
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS
Dated: November 30, 2004
Received: December 6, 2004

Dear Mr. Geremakis:

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.

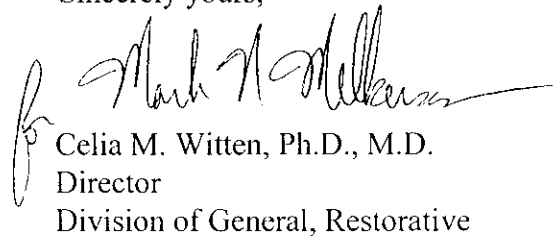
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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INDICATIONS FOR USE

510(k) Number (if known): K043346

Device Name: Genesis Total Shoulder Replacement

Indications for Use:

Total shoulder or hemi-shoulder replacement is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory.
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures.
2. Avascular necrosis of the humeral head.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/or Over-the-Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

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

510(k) Number K043346