K 063578

D.0 Premarket Notification 510(k) Summary

D.1 Submitter Information

MAR 0 2 2007

Company Name and Address:

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Contact Name:

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Date Prepared: November 27, 2006

D.2 Name of Device

2.1 Trade Name: PROMOS® Modular Shoulder System

2.2 Common Name: Hemi- or total shoulder

2.3 Classification Name and Reference:

Title 21 Code of Federal Regulation (CFR), Part 888.3690, prosthesis, shoulder, hemi-, humeral, metallic uncemented
Title 21, CFR, Part 888.3660, prosthesis, shoulder, semi-constrained, metal/polymer cemented

E.3 Substantial Equivalence Claimed to Predicate Device

3.1 PROMOS® Modular Shoulder System, K032126

E.4 Device Description

The modified PROMOS® Modular Shoulder System is intended to aid in the restoration of shoulder motion and elimination of pain. This device consists of two primary components, the glenoid component and the modular humeral component. The changes to the PROMOS® Shoulder that resulted in the modified PROMOS® Shoulder and are subject of this 510(k) include:

- Addition of size 3.5 humeral stem, cementless
- Addition of six humeral ball heads R21 – R26, with 4 mm eccentricity
- Redesign of body and inclination set to add face gear to area between inclination set and body
- Addition of three Monoblock stems, cementless, size 02/30, 35 and 40 mm
- Various labeling changes

The glenoid component has a spherical articulating surface with four pegs on the inferior surface for attachment to the bone. It is manufactured from ultra high molecular weight polyethylene (UHMWPe) according to ISO 5834-2:1998, Implants for Surgery - Ultra-High-Molecular-Weight Polyethylene - Part 2: Moulded Forms. The glenoid is available in four sizes with each size having three different spherical radii of curvature for a total of twelve glenoid components.

The modular humeral component consists of a distal stem, body, inclination set and humeral head. The distal stem is rectangular in cross-sectional shape, previously available in seven cemented and seven cementless sizes, and now available in seven cemented and eight cementless sizes. It is attached to the body via a Morse type taper.

The cementless and cemented stems are fabricated from titanium alloy (Ti6Al4V) according to ISO 5832-3:1996, Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.

The body is made of same titanium alloy as the distal stems and is available in three sizes. The body and inclination set have been redesigned to add a face gear to the area between the inclination set and body. As before the modified inclination set consists of three components: an inclination insert, an offset module, and a ball head screw.

The modular humeral heads are manufactured from wrought cobalt-chromium-molybdenum (CoCrMo) alloy according to ISO 5832-12:1996, Implants for surgery -- Metallic materials -- Part 12: Wrought cobalt-chromium-molybdenum alloy, previously available in eight different sizes/eccentricities, and now available in 14 different sizes/eccentricities.

Since cementless or cemented stems in size 01 may be too large for some patients, the company has developed a humeral stem, size 02. The narrow cross-section of a size 02 stem precluded a modular design, i.e., 02 size stem and a selection of bodies. As a result, the company implemented the size 02 as a Monoblock system with three different heights for body sizes 30mm, 35mm, and 40mm. The design of the cross-section is the same as mentioned above in the description of the distal stem and the stem is made of the same titanium alloy. The proximal portion has also been redesigned to add face gear to the area between inclination set and body.

E.5 Intended Use

The PROMOS® Modular Shoulder System is indicated for:

- Advanced degeneration of the shoulder joint as a result of degenerative, post-traumatic or inflammatory arthritis
- Avascular necrosis of the humeral head
- Complex fractures of the proximal Humerus
- Functional impairment especially in the case of post-traumatic loss of the joint configuration

The humeral component is intended for cemented or cementless use. The glenoid component is for use with bone cement only.

E.6 Predicate Device Comparison of Indications for Use / Intended Use and Technical Characteristics

The comparison of the modified PROMOS® Modular Shoulder System was based on a review of the Design Control documentation for the design changes, relevant aspects of which are included in the company's 510(k) Premarket Notification, and information concerning the predicate device that was available to the company internally, i.e., PROMOS® Modular Shoulder System, K032126. The comparison considered technical characteristics and the indications for use / intended use. Bench testing was assessed.

E.7 Performance Data

7.1 Performance Standards (Section 514 Compliance): no applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act, for prosthesis, shoulder, hemi-, humeral, metallic uncemented or prosthesis, shoulder, semi-constrained, metal/polymer cemented. The modified PROMOS® Modular Shoulder System does conform to the following FDA recognized standards:

7.1.1 Sterility

AAMI / ANSI / ISO 11137:1994, Sterilization of health care products - Requirements for validation and routine control -- radiation sterilization and ANSI/AAMI/ISO 11137:1994 (Amendment 1:2002)

7.1.2 Biocompatibility

ISO 5834-2:1998, Implants for Surgery - Ultra-High-Molecular-Weight Polyethylene - Part 2: Moulded Forms

ISO 5832-3:1996, Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy

ISO 5832-12:1996, Implants for surgery -- Metallic materials -- Part 12: Wrought cobalt-chromium-molybdenum alloy

7.1.3 Performance Testing: Design verification and design validation, e.g., bench testing was performed according to FDA's Design Control Requirements, Title 21 Code of Federal Regulations, Part 820.30.

E.8 **Conclusion**:

The information and data provided in this 510(k) Premarket Notification establish that the modified PROMOS® Modular Shoulder System is substantially equivalent to the afore-mentioned predicate device with respect to indications for use/intended use, and technical characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

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Norfolk, MA 02056

MAR 0 2 2007

Re: K063578
Trade/Device Name: PROMOS® Modular Shoulder System
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
Regulatory Class: II
Product Code: HSD, KWS
Dated: February 2, 2007
Received: February 5, 2007

Dear Ms. Weagraff:

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.

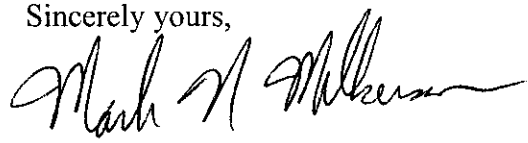
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (240) 276-3150 or at its 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

ODE Indications Statement

510(k) Number (if known): *Unknown* K063578/S001

Device Name: PROMOS® Modular Shoulder System

Indications for Use:

The PROMOS Modular Shoulder System is indicated for:

- Advanced degeneration of the shoulder joint as a result of degenerative, post-traumatic or inflammatory arthritis
- Avascular necrosis of the humeral head
- Complex fractures of the proximal humerus
- Functional impairment especially in the case of post-traumatic loss of the joint configuration

The humeral component is intended for cemented or cementless use. The glenoid component is for use with bone cement only.

Prescription Use: X AND/OR Over-the-Counter Use: _____
(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 K063578