K032126

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510(k) Summary

Date
July 9, 2003

Submitter
PLUS Orthopedics
6055 Lusk Blvd
San Diego, CA 92121

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Common name
Hemi- or total shoulder

Classification name
Prosthesis, shoulder, hemi-, humeral, metallic, uncemented, per 21 CFR Sec. 888.3690
or
Prosthesis, shoulder, semi-constrained, metal/polymer, cemented, per 21 CFR Sec. 888.3660

Device Description
The PROMOS® Shoulder will help in restoring shoulder motion and eliminating pain.

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). 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 humeral component is modular with a distal stem, body, inclination set and humeral head. The distal stem is rectangular in cross sectional shape and available in seven cemented and seven cementless sizes. It is attached to the body via a Morse type taper. Both cemented and cementless stems are fabricated from titanium alloy (Ti6Al4V) that conforms to ISO 5832-3. The body is made of titanium alloy and is available in three sizes. The body has a cavity in the proximal portion to accept the inclination set. The inclination set consists of an insert, offset module and ball screw. The ball screw inserts through the offset module and insert, and the assembly is threaded into the cavity in the body. The offset module can be set at various positions and when the ball screw is tightened into the body the offset module is locked into place. The offset module has a male Morse type taper to which the humeral head is attached. All components of the inclination set are made from titanium alloy. The offset module is available in three different heights resulting in the humeral head being placed at three heights.

The modular humeral heads are manufactured from CoCrMo alloy that conforms to ISO 5832-12. The head is available in eight different sizes.

Intended Use
The PROMOS Shoulder is indicated for:

- Advanced wear of the shoulder joint due to degenerative, post-traumatic or rheumatoid arthritis
- Fracture or avascular necrosis of the humeral head
- Post-traumatic loss of joint configuration, especially in the case of functional impairment
- Humerus fracture

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

Summary of Technological Characteristics Compared to Predicate Device
The PROMOS Shoulder is similar to the Arthrex (Arthrex, Inc.; Naples, FL; K010124) and Anatomical (Sulzer Orthopedics, Inc.; Austin, TX; K990136, K990137, K003801, K003832) Shoulders in terms of material, adjustable inclination of humeral head, and indications for use.

Summary Non-clinical Tests
The results of laboratory testing indicate that the PROMOS Shoulder will survive the expected *in-vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2004

PLUS Orthopedics
C/o Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K032126
Trade/Device Name: PROMOS® Shoulder
Regulation Numbers: 21 CFR 888.3690 and 21 CFR 888.3660
Regulation Names: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis and Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: HSD and KWS
Dated: October 7, 2003
Received: October 10, 2003

Dear Mr. Webb:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

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

510(k) number (if known): K032126

Device Name: PROMOS® Shoulder

Indications for Use:

PROMOS® Shoulder
Indications for Use

The PROMOS® Shoulder is indicated for:

- Advanced wear of the shoulder joint due to degenerative, post-traumatic or rheumatoid arthritis
- Fracture or avascular necrosis of the humeral head
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- Humerus fracture

The humeral component is intended for cemented or cementless use.

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(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, Neurological and Restorative Devices

510(k) Number_____

Prescription Use ✓
(per 21 CFR 801.109) OR Over-the-Counter Use ____

(Optional format 1-2-96) _____

for Mark N. Milkerson
(Division Sign-Off)
Division of General, Neurological and Restorative Devices
(Office) Number K032126