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510(k) Summary

SUBMITTER NAME: Ascension Orthopedics, Inc.
8700 Cameron Road
Austin, TX 78754-3832

AUG 30 2010

510(k) CONTACT: Stanley J. Harris
Phone: (512) 836-5001 x1545

DATE: August 26, 2010

TRADE NAME: Ascension® Modular Total Shoulder System

COMMON NAME: Hemi- or Total shoulder

CLASSIFICATION: 21 CFR 888.3690 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis

21 CFR 888.3660, Shoulder joint metal/polymer semi-constrained cemented prosthesis

PRODUCT CODE: HSD and KWS

PANEL: Orthopedic

PREDICATE DEVICES:
K032126/K063578 - Smith & Nephew/Plus Orthopedics PROMOS Modular Shoulder System

K962082: Osteonics' All Polyethylene Glenoid Shoulder Keeled Components

DEVICE DESCRIPTION:
The Modular Total Shoulder System consists of a line of proximal bodies, humeral stems, humeral heads and all polyethylene glenoid components. The body, stem and humeral head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement. The proximal bodies and humeral stems are manufactured from titanium alloy (Ti6Al4V) and connect together via a Morse type taper. The humeral heads are manufactured from cobalt-chrome-molybdenum (CoCrMo) alloy and are offered in both concentric and eccentric configurations. The humeral head may articulate against the natural glenoid bone if it is of sufficient quality, or against the all polyethylene cemented glenoid. The glenoid is manufactured from ultra high molecular weight polyethylene (UHMWPE) and is offered in a keeled and pegged configuration. Both glenoid options are designed to function with both the concentric and eccentric heads.

INTENDED USE:
The Ascension Modular Total Shoulder System is indicated for use as a hemi or total shoulder replacement for:

1. 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).

Shoulder Hemiarthroplasty is also indicated for:

1. Ununited humeral head fractures.
2. Avascular necrosis of the humeral head.
3. Rotator cuff arthropathy.
4. Deformity and/or limited motion.

The humeral component is intended for cemented or uncemented use. The glenoid component is intended for cemented use only.

SUMMARY OF TECHNOLOGIES:
There are no significant differences between the Ascension® Modular Total Shoulder System, to the Smith & Nephew/Plus Orthopedics PROMOS Modular Shoulder System (K032126/K063578) currently being marketed which would adversely affect the use of the product. It is substantially equivalent to this device in design, function, and intended use.

SUBSTANTIAL EQUIVALENCE:
Substantial equivalence was based upon testing and a geometrical comparison of the subject and predicate devices. Tests performed to substantiate equivalence were: axial disassembly force of taper connections, bending taper fatigue endurance, and dynamic evaluation of glenoid loosening. Geometrical comparisons were between the subject device, Ascension TITAN Modular Total Shoulder System and predicate devices: Smith & Nephew/PLUS PROMOS Modular Shoulder System (K032126, K063578) and the Osteonics' All Polyethylene Glenoid Shoulder Keeled Components (K962082).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ascension Orthopedics, Inc.
% Mr. Stanley J. Harris
Vice President, Clinical/Regulatory Affairs
8700 Cameron Road, Suite 100
Austin, Texas 78754

AUG 30 2010

Re: K100448
Trade/Device Name: Ascension® Modular Total Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS, HSD
Dated: August 10, 2010
Received: August 17, 2010

Dear Mr. Harris:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number: K100448

Device Name: Ascension® Modular Total Shoulder System

Indications for Use:

The Ascension Modular Total Shoulder System is indicated for use as a hemi or total shoulder replacement for:

1. 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.
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Prescription Use ___X___ (Part 21 CFR 801Subpart B) OR Over-The-Counter Use _____ (Part 21 CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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