K06186 page 1 of 4

AUG 28 2006

510(k) Summary
for
Axiom Orthopaedics Shoulder Resurfacing System

1. SPONSOR

Axiom Orthopaedics, Inc.
285 West Side Avenue
Suite 251
Jersey City, NJ 07305

Contact Person: Peter Verrillo
Telephone: 201-377-9129

Date Prepared: June 29, 2006

2. DEVICE NAME

Proprietary Name:	Axiom Orthopaedics Shoulder Resurfacing System
Common/Usual Name:	Shoulder Resurfacing System
Classification Name:	Shoulder joint, humeral (hemi-shoulder), metallic uncemented prosthesis

3. PREDICATE DEVICES

Depuy Global CAP Resurfacing Replacement Shoulder	K033516
Biomet Copeland Resurfacing Humeral Heads	K010657

4. DEVICE DESCRIPTION

The Axiom Orthopaedics Shoulder Resurfacing System is a series of humeral heads that are designed to articulate with a resurfaced or non-resurfaced Glenoid fossa. The proposed humeral heads are manufactured from cobalt chromium alloy (ASTM F-75) and can be used as either a left or right configuration. The interior surface of the proposed Axiom components contains a pattern of buttressed protrusions that help restrict rotation of the device. In addition to the buttressed protrusion pattern, the interior surface is coated with a plasma spray titanium substrate and a calcium phosphate coating (ASTM 1044 and ASTM 1147, respectively).

The proposed humeral heads have been designed to mimic the normal humeral head geometry by employing a non-spherical accurate shape. The shape of the humeral heads does not exceed the radius of curvature of the reamed Glenoid fossa. This helps to maintain contact between the humeral head and the Glenoid fossa throughout the range of motion. The humeral heads are available in 14 sizes.

5. INTENDED USE

The Axiom Orthopaedics Shoulder Resurfacing System is intended as a hemi shoulder replacement in patients where the humeral head and neck are of sufficient bone stock and the rotator cuff is intact or reconstructable. This device will increase shoulder mobility by: reducing pain; restoring alignment; restoring flexion and extension movement; and resisting dislocation.

The Axiom Shoulder Resurfacing System is indicated for use as a replacement of shoulder joints disabled by

- Rheumatoid arthritis with pain
- Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
- Correction of functional deformity
- Fractures of the humeral head
- Traumatic arthritis.

These components are single use only and are intended for cementless use.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed Axiom Orthopaedics Shoulder Resurfacing System, the Depuy Global CAP Resurfacing Replacement Shoulder and the Biomet Copeland Resurfacing Humeral Heads are all identical in that they all consist of humeral heads manufactured from cobalt-chromium-molybdenum alloy that are indicated for uncemented use only. Both the proposed product and the predicate devices are manufactured from cobalt chromium alloy that comply with ASTM F75. The interior surface of both the proposed and predicate device components contain a calcium phosphate coating for cementless use. Both the proposed and predicate devices are cementless humeral replacement systems that require minimal bone resection.

Both the proposed product and the predicate devices have been designed to mimic the normal humeral head geometry. The Depuy predicate devices are available in diameters of 40, 44, 48, 52 and 56mm, all available with head heights of 15mm (short), 18mm (medium) or 21mm (large), and the proposed Axiom product will be available in diameters of 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, and 62 mm with varying thicknesses from 14mm – 24mm.

The only differences between the Axiom device and the predicate devices are that the predicate device includes grooves in the stemmed part of the prosthesis to resist rotation whereas the Axiom device includes fixation features on the inner surface as well as the stemmed part of the head to resist rotation. Additionally, the Depuy predicate device uses a standard spherical method for their articulating surface whereas the proposed device incorporates an elliptical method. These differences do not affect safety or effectiveness of the device since the Axiom device is made of biocompatible materials and is designed similarly to the predicate devices to resist rotation.

7. PERFORMANCE TESTING

A finite element analysis of humeral head loading under a simulated 752 N load was performed to determine the acceptability of the proposed product. The analysis was performed to ensure an acceptable factor of safety with respect to the component material properties, as specified by ASTM F-75. The sizes analyzed represented the smallest, the middle and the largest sizes of the system. The results of this analysis showed that the maximum tensile Von-Mises Keel stress for all of the sizes studied ranges from 170 to 219 MPa. For the given stresses, the factor of safety with respect to the material strength (450 Mpa) ranges from 2.6 to 2.1. The result of this load distribution will be much lower stresses resulting in a higher factor of safety for the Axiom Orthopaedics Shoulder Resurfacing System. The Axiom Orthopaedics Shoulder Resurfacing System components comply with the applicable requirements of the following standards

- F 1044-95, "Standard Test Method for Shear Testing of Porous Metal Coatings"
- F 1147-99, "Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings"

- F1160 – 05 Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings

Additionally, this 510(k) premarket notification was written in consideration of the "Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 28 2006

Axiom Orthopaedics, Inc.
% Ms. Mary McNamara-Cullinane, RAC
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K061862
Trade/Device Name: Axiom Orthopaedics Shoulder Resurfacing System
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: Class II
Product Code: HSD
Dated: June 29, 2006
Received: July 6, 2006

Dear Ms. McNamara-Cullinane:

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" (21 CFR 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,

for

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

Enclosure

510(k) Number (if known): K061862

Device Name: Axiom Orthopaedics Shoulder Resurfacing System

Indications For Use:

The Axiom Orthopaedics Shoulder Resurfacing System is intended as a hemi shoulder replacement in patients where the humeral head and neck are of sufficient bone stock and the rotator cuff is intact or reconstructable. This device will increase shoulder mobility by reducing pain, restoring alignment, restoring flexion and extension movement, and resisting dislocation.

The Axiom Orthopaedics Shoulder Resurfacing System is indicated for use as a replacement of shoulder joints disabled by

1. Rheumatoid arthritis with pain
2. Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
3. Correction of functional deformity
4. Fractures of the humeral head
5. Traumatic arthritis.

These components are single use only and are intended for cementless use.

Prescription Use ___x_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use__No_ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucinski

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

510(k) Number K061862