K030259

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# 510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Sulzer Orthopedics Anatomica Humeral Stem/Heads.

**Manufacturer:**
Centerpulse Orthopedics Ltd.
Grabenstrasse 25
CH 6341 Baar, Switzerland

**US Designated Agent:**
Centerpulse Orthopedics Inc.
9900 Spectrum Drive
Austin, Texas 78717
(512) 432-9900

**Date:**
January 17, 2003

**Contact Person:**
Audrey Swearingen, RAC
Program Manager, Regulatory Affairs

**Classification Name:**
Shoulder joint metal/polymer semi-constrained cemented prosthesis – 21 CFR 888.3660; and

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

**Common/Usual Name:**
Humeral Stem and Head Components

**Trade/Proprietary Name:**
Centerpulse Orthopedics Anatomical Shoulder™ System with Removable Head

**Specific Diagnostic Indications:**

Anatomical Shoulder™ System with Removable Head is intended for use in treatment of the following:

1. Advanced wear and tear of the shoulder joint resulting from degenerative, posttraumatic or rheumatoid arthritis.
2. Omarthrosis.
3. Rheumatoid arthritis.
4. Revision of shoulder prosthesis.
5. Traumatology: the only cone to be used in traumatological indications is the traumatology cone.

**Product Description:**

The system consists of the following:

- Humeral stem, uncemented
- Humeral stem, cemented
- Humeral stem, revision, cemented
- Ball-cone with taper

- Glenoid
- Humeral head

The Anatomical Shoulder™ System with Removable Head was designed to enable the surgeon to remove the head, including the sphere-to-sphere connection, from the stem at any time. This is possible due to the introduction of an oval cone connection. The head is removable in order to gain access to the glenoid or to select other types of humeral heads.

Humeral Stem

The cemented stem is manufactured of cast cobalt-chromium-molybdenum alloy, CoCrMo. The uncemented stem is made of forged titanium alloy, Ti6Al7Nb. Both stems are offered in four sizes based on the distal diameter of the stem. The cemented revision stems are extended in length by 100 mm. The stem is straight and features a "trumpet shaped" proximal geometry to match the metaphysis of the humeral shaft. Rotational stability is achieved via the proximal fin. The proximal and medial portions of the stem body also feature a hole for placement of a wire or strong suture, if needed, for refixation of the tuberosities.

Ball-taper

The ball-taper component is made from forged titanium alloy. The ball-cone of the Anatomical Shoulder with Removable Head is a separate component The ball-taper features a slit cone on one side and an oval cone on the other, and is identical for all sizes of stems. Either the standard cone or fracture cone is introduced into the ball-taper component, and an impact screw is utilized to expand the slit oval cone for attachment to the selected modular humeral head. The fixation is secured against rotation by means of the oval conical coupling.

Humeral Head

The humeral heads used with the Anatomical Shoulder with Removable Head are the same as those used with the existing cleared Anatomical Shoulder System.

Glenoid

The glenoid used with the Anatomical Shoulder with Removable Head is the same as that used with the existing cleared Anatomical Shoulder System.

**Substantial Equivalence:**

The Centerpulse Orthopedics Anatomical Shoulder System with Removable Head is substantially equivalent to the Sulzer (Centerpulse) Orthopedics Anatomical Press-Fit Humeral Stem (K003801) and cemented Anatomical Humeral Stem/Head (K990137, K003832), as well as to the Sulzer (Centerpulse) Orthopedics Select Shoulder, the Kirschner/Biomet Mod II-C Shoulder, the Biomet Bio-Modular Total Shoulder, and the Depuy Global Advantage Shoulder System.

Design verification testing did not raise any new issues of safety or effectiveness and indicated that this device should provide performance equivalent to commercially marketed products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2003

Ms. Audrey Swearingen, RAC
Regulatory Affairs Manager
Centerpulse Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K030259
Trade/Device Name: Centerpulse Orthopedics Anatomical Shoulder™ System with Removable Head
Regulation Number: 21 CFR 888.3660 and 888.3690
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis and Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: II
Product Code: KWS and HSD
Dated: January 21, 2003
Received: January 24, 2003

Dear Ms. Swearingen:

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

K030259



**510(k) Number (if known):**

**Device Name: Anatomical Shoulder™ System with Removable Heads**

## Indications for Use Statement:

The Centerpulse Orthopedics Anatomical Shoulder™ System with Removable Head is intended for use in treatment of the following:

1. Advanced wear of the shoulder joint resulting from degenerative, post-traumatic or rheumatic arthritis
2. Omarthrosis
3. Rheumatoid arthritis
4. Revision of shoulder prosthesis.
5. Traumatology: the only cone to be used in traumatological indications is the traumatology cone.

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

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

for Mark N Milhous

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

510(k) Number K030259

**Prescription Use** _____ **OR** **Over-The-Counter Use**