 K040803 (pg 1 of 1)

APR 2 9 2004

510(k) SUMMARY

SPONSOR NAME: Centerpulse Orthopedics, Inc.
9900 Spectrum Drive
Austin, TX 78717

510(k) CONTACT: Robert M. Wolfarth
Phone: (512) 432-9324
E-Mail: Robert.Wolfarth@Zimmer.com

TRADE NAME: MS-30 Femoral Stem, Standard and Lateral

COMMON NAME: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

CLASSIFICATION: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prostheses (Product Code 87 LZO) are Class II per 21 CFR §888.3353, reviewed by the Orthopedic Devices panel.

PREDICATE DEVICES:

MS-30 Femoral Stem standard: K993043, K001078
MS-30 Femoral Stem lateral: K020713

DEVICE DESCRIPTION:

The MS-30 Stem is a highly polished, collarless femoral component manufactured from forged stainless steel alloy. It is available in six standard sizes and six lateral sizes. The lateral version offers the surgeon a 12% offset versus the standard version. The MS-30 Stem is intended for cemented use.

INTENDED USE:

The MS-30 Femoral Stem is intended for cemented use in treatment of the following:

- Advanced wear of the joint due to degenerative, posttraumatic or rheumatic diseases.
- Fractures or vascular necroses.
- Status following earlier operations, such as joint reconstruction (osteotomy), arthrodesis, hemiarthroplasty of total hip prosthesis (THP).

BASIS OF SUBSTANTIAL EQUIVALENCE:

Performance tests, design comparisons, and functional analyses conducted on the MS-30 Femoral Stem demonstrate that it is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2004

Mr. Robert M. Wolfarth
Regulatory Affairs Programs Manager
Zimmer, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K040803
Trade/Device Name: MS-30 Femoral Stem Standard and Lateral
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prostheses
Regulatory Class: II
Product Code: LZO
Dated: March 26, 2004
Received: March 30, 2004

Dear Mr. Wolfarth:

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

Indications for Use

510(k) Number (if known):_____

Device Name: MS-30 Femoral Stem Standard and Lateral

Indications For Use:

The MS-30 Femoral Stem is intended for cemented use in treatment of the following:

- Advanced wear of the joint due to degenerative, posttraumatic or rheumatic diseases.
- Fractures or vascular necroses.
- Status following earlier operations, such as joint reconstruction (osteotomy), arthrodesis, hemiarthroplasty of total hip prosthesis (THP).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

for Mark N Milham

(Division Sign-Off) Page 1 of ____

Division of General, Restorative, and Neurological Devices

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