K033664

DEC 17 2003

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 Centerpulse Orthopedics Ltd. Alloclassic™ Zweymüller™ SL Offset Femoral Stem.

Manufacturer:	Centerpulse Orthopedics Ltd. Altgasse 44 CH-6340 Baar, Switzerland
US Distributor:	Centerpulse Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	November 20, 2003
Contact Person:	Jean Asquith Regulatory Affairs Specialist (512) 432-9900 X8212
Classification Name:	21 CFR Part 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Common/Usual Name:	Femoral Hip Stem
Trade/Proprietary Name:	Alloclassic™ Zweymüller™ SL Offset Femoral Stem

PRODUCT DESCRIPTION

The Alloclassic Zweymüller SL Offset Femoral Stem is very similar to the previously cleared Alloclassic Zweymüller SL Femoral Stem in that it is:

1. a conically shaped straight stem with a rectangular cross section (for rotational stability).
2. the same design, distal to the line of resection.
3. manufactured from wrought Ti-Al-Nb titanium alloy (Protasul-100™, ISO 5832-11/ASTM F1295).
4. grit blasted, below the neck, to enhance the bone-prosthesis interface.

In contrast, this stem provides an additional 6.25mm of offset (per size) and has a CCD/neck angle of 121° (vs. 131° for SL stem). Overall, this new design provides a higher offset sometimes needed for:

1. correcting insufficient soft tissue balancing,
2. restoration of leg length, and
3. sufficient joint stability following total hip arthroplasty.

SPECIFIC DIAGNOSTIC INDICATIONS

There have been no changes in the diagnostic indications for use as compared to the unmodified device.

The Alloclassic Zweymüller SL Offset Femoral Stem is intended for non-cemented use to replace the anatomy of the femur in cases of total hip replacement. It is intended to be used with Centerpulse Orthopedics acetabular components and metallic or ceramic femoral heads possessing a 12/14 taper.

The indications for use of the Alloclassic Zweymüller SL Offset Femoral Stem are for treatment of the following:

- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- revision of a previously failed hip arthroplasty.
- patients who require a total hip replacement.

SUBSTANTIAL EQUIVALENCE

Therefore, based on the information provided, Centerpulse Orthopedics believes the Alloclassic Zweymüller SL Offset Femoral Stem is substantially equivalent to the previously cleared, Zweymüller SL Femoral Stem (ref. K030373 as Exhibit 3) as it has the same indications for use, basic design, sizes, material, sterilization method, and method of manufacture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2003

Ms. Jean Asquith
Regulatory Affairs Specialist
Centerpulse Orthopedics Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K033664
Trade/Device Name: Alloclassic™ Zweymüller™ SL Offset Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Codes: LZO, JDI, KWY, KWL
Dated: November 20, 2003
Received: November 21, 2003

Dear Ms. Asquith:

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 Milhern

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): K033664

Device Name: **Alloclassic SL Offset Femoral Stem**

Indications for Use:

The Alloclassic SL Offset Femoral Stem is intended for prosthetic replacement without bone cement in treatment of the following:

- patient conditions of noninflammatory degenerative joint disease (NIDJD); e.g., avascular necrosis, osteoarthritis and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- revision of a previously failed hip arthroplasty.
- patients who require a total hip replacement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

for Mark N Milhous

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

510(k) Number K033664

(Optional Format 1-2-96)