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™ Zweymueller™ SL/SLL Femoral Stem.

Manufacturer: Centerpulse Orthopedics Ltd.
Altgasse 44
CH-6340 Baar, Switzerland

MAR 0 6 2003

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

Date: January 31, 2003

Contact Person: Audrey Swearingen, RAC
Manager, Regulatory Affairs
(512) 432-9255

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™ Zweymueller™ SL/SLL Femoral Stem

PRODUCT DESCRIPTION

The Alloclassic™ Zweymueller™ SL/SLL Femoral Stem is designed as a conical straight stem with a rectangular cross section to ensure rotational stability. Distally the SLL stem is up to 20% longer than the same size SL stem, while maintaining the same conical features. This provides the surgeon with greater freedom of choice even in primary operations. A SLL stem of the same size as the pre-selected SL stem can be implanted to achieve primary stability in cases of unexpected poor bone quality. Distally the stem is anchored primarily by its edges; proximally the surfaces anchor against the bone cortex.

The general design of the Alloclassic™ Zweymueller™ SL/SLL Femoral Stem with the slim neck and short taper remains unchanged as compared to the design of the previously cleared Zweymueller™ SL Femoral Stem.

The modified design increases the patient's range of motion by up to 12° following a total hip replacement. The risk of impingement and ultimately the risk of dislocation are reduced following a total hip replacement.

The Alloclassic™ Zweymueller™ SL/SLL Femoral Stem is manufactured from wrought Ti-Al-Nb titanium alloy (Protasul-100™, ISO 5832-11 / ASTM F1295-92). The entire stem below the neck of the hip stem is grit blasted to provide enhanced bone/prosthesis interface.

SPECIFIC DIAGNOSTIC INDICATIONS

There have been no changes in the diagnostic indications for use of the previously cleared device as a result of this modification.

The Alloclassic™ Zweymueller® SL/SLL 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™ Zweymueller® SL/SLL 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™ Zweymueller™ SL/SLL Femoral Stem is substantially equivalent to the previously cleared, Zweymueller™ SL Femoral Stem (ref. K962101 as Exhibit 9) 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

MAR 0 6 2003

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

Re: K030373
Trade/Device Name: Alloclassic™ Zweymueller™ SL/SLL Femoral Stem
Regulation Numbers: 21 CFR 888.3353
Regulation Names: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO, JDI, KWY, KWL
Dated: January 31, 2003
Received: February 4, 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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 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): K030373

Device Name: Alloclassic™ Zweymueller ™ SL/SLL Femoral Stem

Indications for Use:

The Alloclassic™ Zweymueller™ SL/SLL 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 requires 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**

Mark N Millerson

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

510(k) Number K030373

(Optional Format 1-2-96)