

**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@Centerpulse.com

**TRADE NAME:** Wagner Cone Prosthesis

**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:**

- MPT™ Reconstruction Hip Stem by Waldemar Link GmbH & Co KG. (K955296)
- Restoration™ Modular System by Howmedica Osteonics Corp. (K022549)
- Wagner Revision Stem (K960588)
- Precedent Revision Hip Stem (K972637)

**DEVICE DESCRIPTION:**

This stem is a titanium-aluminum-niobium alloy conical configuration with a taper. The design features a circular cross-section with eight equally spaced conical longitudinal flutes down the long axis of the stem for rotational stability. The stem's core diameter tapers gradually from the proximal end to the distal end.

**INTENDED USE:**

The Wagner Cone Prosthesis is intended for prosthetic replacement of the proximal portion of the femur in total hip arthroplasty. This device is intended for cementless application where primary fixation occurs predominantly in the distal region. Specific diagnostic indications for use of the Wagner Cone Prosthesis are:

- 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 previously failed hip arthroplasty.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

Performance tests, design comparisons, and functional analyses conducted on the Wagner Cone Prosthesis demonstrate that it is substantially equivalent to the predicate devices.



SEP 22 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Robert M. Wolfarth  
Regulatory Affairs Programs Manager  
Centerpulse Orthopedics, Inc.  
9900 Spectrum Drive  
Austin, TX 78717

Re: K032380

Trade/Device Name: Wagner Cone Prosthesis  
Regulation Number: 21 CFR 888.3353  
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or  
nonporous uncemented prosthesis  
Regulatory Class: II  
Product Code: LZO  
Dated: July 30, 2003  
Received: August 1, 2003

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.

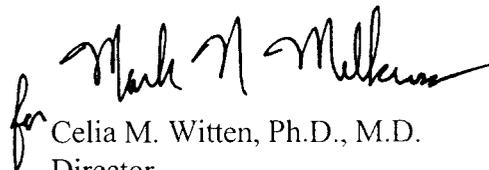
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Mr. Robert M. Wolfarth

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

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: \_\_\_\_\_

Device Name: Wagner Cone Prosthesis

Indications for Use:

The Wagner Cone Prosthesis is intended for prosthetic replacement of the proximal portion of the femur in total hip arthroplasty. This device is intended for cementless application where primary fixation occurs predominantly in the distal region. Specific diagnostic indications for use of the Wagner Cone Prosthesis are:

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- those patients with failed previous surgery where pain, deformity, or dysfunction persists;
- revision of previously failed hip arthroplasty.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

*for Mark A. Milken*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

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