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K032348

OCT 2 4 2003

# 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:** Converge RETi-Lock Multi-Hole Reinforcement Cup

**COMMON NAME:** Non-porous, press-fit, acetabular shell system

**CLASSIFICATION:** Non-porous, press-fit, acetabular shell systems (Product Codes 87 LZO, KWA, JDI, LWJ) are Class II per 21 CFR §§888.3353, .3330, and .3350 respectively, reviewed by the Orthopedic Devices panel.

**PREDICATE DEVICES:**

- Ascendant Acetabular System (K022985)
- Restoration GAP II Cup (K980774)

**DEVICE DESCRIPTION:**

The Converge RETi-Lock Multi-Hole Reinforcement Cup is a hemispherical acetabular reinforcement shell made of titanium alloy. It is designed to expand the surgeon's options for treatment in cases when acetabular bone stock is deficient. This device also has a fixation plate designed to match the contour of the ilium of the acetabulum and a hook designed to attach to the obturator foramen. Numerous screw holes in the cup and along the plate help to ensure fixation in good bone stock.

**INTENDED USE:**

The Converge RETi-Lock Multi-Hole Reinforcement Cup is intended for use in total hip arthroplasty 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 previously failed hip arthroplasty.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

Performance testing, design comparisons, and functional analyses conducted on the Converge RETi-Lock Multi-Hole Reinforcement Cup demonstrate that this device 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

OCT 24 2003

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

Re: K032348
Trade/Device Name: Converge RETi-Lock Multi-Hole Reinforcement Cup
Regulation Numbers: 21 CFR 888.3353; 21 CFR 888.3330; 21 CFR 888.3350
Regulation Names: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis; Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II, III, II
Product Codes: LZO, KWA, JDI, LWJ
Dated: July 29, 2003
Received: July 31, 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.

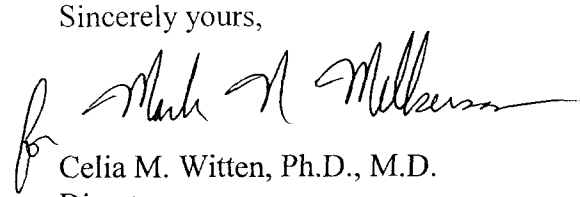
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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.

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,



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*: K032348

*Device Name*: Converge RETi-Lock Multi-Hole Reinforcement Cup

*Indications for Use*:

The Converge RETi-Lock Multi-Hole Reinforcement Cup is intended for use in total hip arthroplasty 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 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 _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K032348

(Optional Format 1-2-96)