K030923

OCT - 3 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
Robert.Wolfarth@Centerpulse.com

TRADE NAME: Epsilon™ Durasul® Constrained Acetabular Liner
COMMON NAME: Constrained Acetabular Insert
CLASSIFICATION: Constrained Acetabular Inserts (87 KWZ) are Class II per 21 CFR §888.3310, reviewed by the Orthopedic Devices panel.

PREDICATE DEVICES:

- Johnson & Johnson DePuy S-ROM Poly-Dial Constrained Liner (P960054)
- Stryker/Howmedica/Osteonics Omnifit Constrained Liner (P960047)
- Biomet Ringloc Constrained Liner (K021661)

DEVICE DESCRIPTION:
This device consists of two components: a liner and a ring, which will be assembled and attached to one of the corresponding Centerpulse Orthopedics Inc. acetabular shells. The liner mates with previously-cleared Centerpulse Orthopedics Inc. acetabular shell components via a snap lock mechanism. The metallic reinforcing ring provides added femoral head constraint once assembled. The fixation method of the acetabular components is porous cementless with supplemental screws, and the fixation method of the femoral components is cemented, porous cementless, or non-porous cementless fixation, as indicated for use by each respective femoral component. At the time of surgery, the constrained liner and ring will be assembled to the corresponding acetabular shell and femoral head.

INTENDED USE:
The Epsilon™ Durasul® Constrained Acetabular Liner is intended for use in treatment of primary or revision total hip arthroplasties where there is a high risk of hip dislocation due to a history of instability, bone loss, joint, muscle, or tissue laxity, or disease condition. This device is intended for patients for whom all other options to constrained acetabular components have been considered. The fixation method of the acetabular components with which this device is intended to be used is porous cementless with supplemental screws, and the fixation method of the femoral components with which this device is intended to be used is cemented, porous cementless, or non-porous cementless fixation, as indicated for use by each respective femoral component.

BASIS OF SUBSTANTIAL EQUIVALENCE:
Performance tests, design comparisons, and functional analyses conducted on the Epsilon™ Durasul® Constrained Acetabular Liner demonstrate that this device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2003

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

Re: K030923
Trade Name: Epsilon™ Durasul® Constrained Acetabular Liner
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWZ
Dated: July 7, 2003
Received: July 9, 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,

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: K030923

Device Name: Epsilon™ Durasul® Constrained Acetabular Insert

Indications for Use:
The Epsilon™ Durasul® Constrained Acetabular Insert is intended for use in treatment of primary or revision total hip arthroplasties where there is a high risk of hip dislocation due to a history of instability, bone loss, joint, muscle, or tissue laxity, or disease condition. This device is intended for patients for whom all other options to constrained acetabular components have been considered. The fixation method of the acetabular components with which this device is intended to be used is porous cementless with supplemental screws, and the fixation method of the femoral components with which this device is intended to be used is cemented, porous cementless, or non-porous cementless fixation, as indicated for use by each respective femoral component.

(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)

(Optional Format 1-2-96)

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

510(k) Number K030923