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K033810

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510(k) SUMMARY

SPONSOR NAME: Centerpulse Orthopedics, Inc., a division of Zimmer
9900 Spectrum Drive
Austin, TX 78717

CONTACT: Audrey Swearingen
Phone: (512) 432-9255
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TRADE NAME: Natural-Knee® II Unicompartmental Knee System

COMMON NAME: Unicompartmental Knee

CLASSIFICATION: Unicompartmental Knees are Class II, reviewed by the Orthopedic Devices panel, per 21 CFR §888.3530 and §888.3535.

PREDICATE DEVICES:
The predicate devices chosen to demonstrate substantial equivalence are:

- Natural-Knee II Unicompartmental Knee System (K955778)
- Natural-Knee Unicompartmental Knee System (K883969)
- Natural-Knee II Total Knee System with CSTi (P940002)
- Wright Medical ADVANCE® Unicompartmental Knee (K012591)
- DePuy Preservation™ Unicompartmental Knee (K010810)
- Plus Orthopedics UC Plus™ Unicompartmental Knee (K982859)

DEVICE DESCRIPTION:
The Natural-Knee II Unicompartmental Knee System is a conservative, cost-effective alternative to total knee replacement for patients with osteoarthritis primarily confined to one compartment. The N-K II Unicompartmental Knee System is intended for resurfacing of one side of the knee joint.

The N-K II Unicompartmental Modular Metal-backed Tibia is similar to the previously cleared N-K II Unicompartmental Tibia (K955778). The wrought titanium alloy tibial baseplate is a symmetrically designed component, eliminating the need for left/right orientations. The baseplate features three smooth pegs on the underside which aid in positioning and rotational stability. A smooth surface finish is provided on the inner surface of the tibial tray to minimize the potential for polyethylene wear. A screw hole is placed in the center of the baseplate for optional screw fixation. The baseplate is available in either a porous or non-porous version.

The all-poly tibia is designed with a single keel to position the component on the tibia and increase stability. Cement grooves on both the medial and lateral side of the keel increase the anchoring effect of the keel, while a dovetail cement channel around the perimeter of the distal surface, along with a T-pattern dovetail cement channel, act to resist movement in all directions. It is to be used only with bone cement for application directly onto the patient's resected proximal tibia.

The metal-backed and the all-poly tibias are both available in 6 sizes (1-6). The modular

metal-backed tibia will be offered in 3 thicknesses (9, 11, and 13 mm). The insert thickness reflects the total amount of bone to be resected. The all-poly insert will be available in 4 thicknesses (7, 9, 11, and 13mm), in which the thickness is measured at the thinnest point from the distal to the proximal surface of the component.

The design of the femoral component of the proposed N-K II Unicompartmental Knee System will not change. This premarket notification only seeks to obtain clearance for the addition of cementless use of the previously cleared porous-coated femur (K955778).

INTENDED USE:
The Natural-Knee II Unicompartmental Knee is intended for use in:

1. Unicompartmental noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis and arthritis secondary to a variety of diseases and anomalies;
2. Passively correctable valgus-varus deformity and moderate flexion contracture;
3. Those patients with failed previous surgery where pain, deformity or dysfunction persists.

These indications for use are identical to the indications for the previously cleared Natural-Knee II Unicompartmental System (K955778) and Natural Knee Unicompartmental System (K883969).

The proposed N-K II Unicompartmental All-Poly Tibia is intended to be used only with bone cement. The N-K II Unicompartmental Modular Tibia and Femur are intended for use with or without bone cement.

BASIS OF SUBSTANTIAL EQUIVALENCE:
Comparisons of device design features, indications for use, materials and labeling of the Natural-Knee II Unicompartmental Knee System demonstrate that it is substantially equivalent to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 2004

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

Re: K033810
Trade/Device Name: Natural-Knee® II Unicompartmental Knee System
Regulation Numbers: 21 CFR 888.3530 and 21 CFR 888.3535
Regulation Names: Knee joint, femorotibial, metal/polymer semi-constrained cemented Prosthesis, Knee joint, femorotibial (unicompartmental) metal/polymer porous-coated uncemented prosthesis
Regulatory Class: II
Product Codes: HRY, NJD
Dated: December 5, 2003
Received: December 8, 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. 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 (if known): K033810

Device Name: Natural-Knee® II Unicompartmental Knee System

Indications For Use: The Natural-Knee II Unicompartmental Knee is intended for use in:

1. Unicompartmental noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis and arthritis secondary to a variety of diseases and anomalies;
2. Passively correctable valgus-varus deformity and moderate flexion contracture;
3. Those patients with failed previous surgery where pain, deformity or dysfunction persists.

The N-K II Unicompartmental All-Poly Tibia is intended to be used only with bone cement. The modular metal/polymer N-K II Unicompartmental Tibia and Femur are intended for use with or without bone cement.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K033810