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K023528

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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 Natural-Knee® II Cemented Modular Tibial Baseplate.

Manufacturer:	Centerpulse Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	October 18, 2002
Contact Person:	Mitchell A. Dhority Manager, Regulatory Affairs
Classification Name:	21 CFR Part 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Common/Usual Name:	Nonporous, Cemented Modular Tibial Baseplate
Trade/Proprietary Name:	Natural-Knee® II Cemented Modular Tibial Baseplate

PRODUCT DESCRIPTION

The Natural-Knee II Cemented Tibial Baseplate is an asymmetrically oriented (e.g. both left and right orientations), nonporous component manufactured from cast CoCr alloy (ASTM F75).

The baseplate is designed to mate with all previously cleared tibial insert components of the Natural-Knee/Natural-Knee II System via capture features on the anterior rim and posterior plateau rims. As such, the baseplate incorporates the snap lock design from the previously cleared Natural-Knee II tibial baseplates. A slot has also been incorporated into the center of the base of the tray to allow for seating of the metal reinforcement pin of the previously cleared Natural-Knee II Constrained/Revision tibial inserts.

The cruciform stem portion of the baseplate is designed to accept one of the previously cleared stems used with the Natural-Knee II System (smooth straight, fluted straight, fluted offset). The baseplate stem boss incorporates the stem connection design of the previously cleared Natural-Knee II Revision Femoral Component. This connection design includes an inner female taper for primary attachment of the stem. Supplemental secondary stem fixation may be achieved by placing the stem attachment screw through the recessed hole in the baseplate and into the screw hole in the stem. The rounded, baseplate stem hole plug designed for use with this component may also be used if a stem is not desired. Unlike the stems, the plug does not possess a taper and is attached to the baseplate solely via the stem attachment screw previously described.

The inferior surface of the baseplate has cement pockets that are grit blasted to enhance cement fixation. The three fins of the stem boss aid in maintaining rotational stability.

SPECIFIC DIAGNOSTIC INDICATIONS

The Natural-Knee II Cemented Modular Tibial Baseplate is intended for cemented use only in total knee arthroplasty for treatment of the following conditions:

1. Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.

2. Correctable valgus-varus deformity and moderate flexion contracture.

3. Those patients with failed previous surgery where pain, deformity or dysfunction persists.

SUBSTANTIAL EQUIVALENCE

The Natural-Knee II Cemented Tibial Baseplate is similar to the following commercially available devices in terms of general design, materials, intended use and indications for use:

- Natural-Knee II System CoCr Tibial Baseplate
- Stryker/Osteonics/Howmedica Duracon
- Stryker/Osteonics/Howmedica Scorpio
- Wright Medical Advance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2003

Mr. Mitchell A. Dhority
Manager, Regulatory Affairs
Centerpulse Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K023528
Trade/Device Name: Natural-Knee® II Cemented Modular Tibial Baseplate
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: October 18, 2002
Received: October 21, 2002

Dear Mr. Mitchell:

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). 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): K023528

Device Name: Natural-Knee II® System Cemented Modular Tibial Baseplate

Indications for Use:

The Natural-Knee II Cemented Modular Tibial Baseplate is intended for cemented use only in total knee arthroplasty for treatment of the following conditions:

1. Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
2. Correctable valgus-varus deformity and moderate flexion contracture.
3. Those patients with failed previous surgery where pain, deformity or dysfunction persists.

(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**

(Optional Format 1-2-96)

for Mark N Milhous

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

510(k) Number K023528