K971497

510(K) PREMARKET NOTIFICATION SUMMARY OF SAFETY AND EFFECTIVENESS OSTEONICS® ANTEVERTED NECK HIP STEM

JUL 16 1997

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:

Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677
201-825-4900

Contact Person:

Donna S. Wilson
Regulatory Affairs Specialist

Date Summary Prepared:

April 23, 1997

Device Identification

Proprietary Name:

Osteonics® Anteverted Neck Hip Stem

Common Name:

Hip Prosthesis

Classification Name and Reference:

Hip Joint, Metal/Polymer/Metal, Semi-Constrained, Porous Coated, Uncemented Prosthesis; 21 CFR §888.3358

Predicate Device Identification

The Osteonics® Anteverted Neck Hip Stems are substantially equivalent to the Osteonics® Omnifit® AD Hip Stem Series, and the Zimmer® Anatomic Hip Prosthesis (including CP, BR, and LS versions).

Device Description

The Osteonics® Anteverted Neck Hip Stems are fabricated from forged ASTM F-620 Titanium 6Al-4V ELI alloy, employ a standard satin finish, and have a surface coating of arc deposited commercially pure (CP) Titanium (per ASTM F-67) on the proximal third of the femoral stem. The basic design characteristics of the Osteonics® Anteverted Neck Hip Stems include proportional stem sizes, maximized projected proximal area, proximal anterior and posterior normalizations, and an Osteonics® C-Taper trunnion. A reduced anterior/posterior collar is present to resist potential subsidence of the stem. The Osteonics® Anteverted Neck Hip Stems feature a rounded configuration for the length of the stem's lateral aspect and a cylindrical distal cross-section, thereby providing physiological fit in the distal as well as proximal regions of the femur. The subject hip stems are available in three proportional sizes, with distal diameters and

stem lengths proportionate to the stem's size, and are available in both left and right configurations. Each hip stem features a 15° anteverted neck angle to satisfy anatomic considerations and physician need.

Intended Use

The Osteonics® Anteverted Neck Hip Stem is intended for single use in patients requiring either a bipolar hip replacement or a total hip replacement. The Osteonics® Anteverted Neck Hip Stem is intended to be implanted in a cementless application. The indications for the use of the Osteonics® Anteverted Neck Hip Stem, in keeping with those of other legally marketed Class II hip stems, are as follows:

For use as a Bipolar Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.

For use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Statement of Technological Comparison

The Osteonics® Anteverted Neck Hip Stems share the same materials, indications and intended use, surgical techniques, basic design features, and basic manufacturing methods of their predicate devices. Applicable performance testing demonstrates that no significant difference exists between these components and their predicate designs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Robert A. Koch, J.D.
Director, Regulatory/Legal Affairs
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

JUL 16 1997

Re: K971497
Osteonics® Anteverted Neck Hip Stem
Regulatory Class: II
Product Codes: LZO, LPH, KWY
Dated: April 23, 1997
Received: April 24, 1997

Dear Mr. Koch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation that the package insert must reflect that the C-taper Zirconia Ceramic Femoral Heads are to be used only with Ti6Al4V alloy hip stems with the C-taper dimensions (5°39'22") trunnions.

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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be

obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 971497

Device Name: Osteonics® Anteverted Neck Hip Stem

Indications For Use:

The Osteonics® Anteverted Neck Hip Stems are intended for single use in patients requiring either a bipolar hip replacement or a total hip replacement. The Osteonics® Anteverted Neck Hip Stems are intended to be implanted in a cementless application. These devices feature an Osteonics® C-Taper trunnion, and are therefore compatible with any Osteonics® component which features the mating Osteonics® C-Taper geometry. The Osteonics® Anteverted Neck Hip Stems, when used with any commercially available Osteonics® C-Taper femoral bearing head, may be used with any commercially available Osteonics® acetabular component. The indications for the use of the Osteonics® Anteverted Neck Hip Stems, in keeping with those of other legally marketed Class II hip stems, are as follows:

For use as a Bipolar Hip Replacement:

- Femoral head/neck fractures or non-unions.
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(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 Devices
510(k) Number K971497

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)