

MAY 27 1998

Osteonics® Anteverted Neck HA Hip Stems

K98 0766
510(k) Premarket Notification

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

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:

February 27, 1998

Device Identification

Proprietary Name:

Osteonics® Anteverted Neck HA Hip Stems

Common Name:

Hip Prosthesis

Classification Name and Reference:

Hip Joint, Metal/Ceramic/Polymer, Semi-
Constrained, Cemented or Non-Porous
Uncemented Prosthesis; 21 CFR §888.3353

Predicate Device Identification

The Osteonics® Anteverted Neck HA Hip Stems are substantially equivalent to the Osteonics® Anteverted Neck Hip Stems and the Osteonics® Secur-Fit HA Plus Hip Stem Series.

Device Description

The Osteonics® Anteverted Neck HA Hip Stems are fabricated from forged Titanium 6Al-4V ELI alloy and have a surface coating of arc deposited commercially pure (CP) Titanium on the proximal third of the femoral stem, and an HA coating on the full length of the stem. The basic design characteristics of the Osteonics® Anteverted Neck HA Hip Stems include proportional stem sizes, maximized projected proximal area, proximal anterior and posterior normalizations, Osteonics® C-Taper trunnion, reduced anterior/posterior collar, rounded configuration for the length of the stem's lateral aspect, cylindrical distal cross-section, left and right configurations, and 15° anteverted neck angle.

Intended Use

The Osteonics® Anteverted Neck HA Hip Stem is intended for single use in patients requiring either bipolar, hemi- or total hip replacement. The Osteonics® Anteverted Neck HA Hip Stem is intended

to be implanted in a cementless application. The indications for the use of the Osteonics® Anteverted Neck HA Hip Stem, in keeping with those of other legally marketed Class II hip stems, are as follows:

For use as a Bipolar/Hemi- 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 HA 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 1998

Ms. Elizabeth A. Staub
Director
Quality Assurance and Regulatory Affairs
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K980766
Trade Name: Anteverted Neck HA Hip Stem
Regulatory Class: II
Product Code: MEH
Dated: February 27, 1998
Received: February 27, 1998

Dear Ms. Staub:

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). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

You may not label or in any way promote these devices for "biological attachment, enhanced clinical or radiographic performance, enhanced fixation and/or long-term stable fixation." The data presented support equivalence with no additional claims over a conventional press-fit hip prosthesis (i.e., mechanical interlock, only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

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.

You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

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. 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.

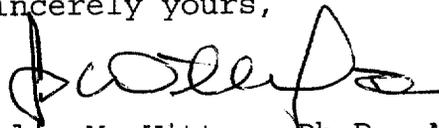
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the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

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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,


f 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): K980766

Device Name: Osteonics® Anteverted Neck HA Hip Stems

Indications For Use:

The Osteonics® Anteverted Neck HA Hip Stems are intended for single use in patients requiring either bipolar, hemi- or total hip replacement. The Osteonics® Anteverted Neck HA 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 HA 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 HA Hip Stems, in keeping with those of other legally marketed Class II hip stems, are as follows:

For use as a Bipolar/Hemi- Hip Replacement:

- Femoral head/neck fractures or non-unions.
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- 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.

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- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

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

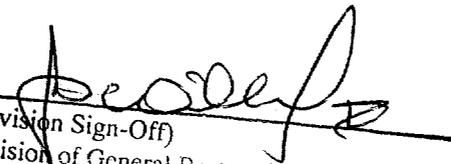
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)


 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K980766