510(k) Summary
Osteonics® Omnifit®-C Cemented Hip Stems

Submission Information

Name and Address of the Sponsor: Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Contact Person: Terry Sheridan
Regulatory Affairs Specialist

Date of Summary Preparation: June 30, 1997

Device Identification

Proprietary Name: Osteonics® Omnifit®-C Cemented Hip Stems (Line Extension)

Common Name: Artificial hip joint component, femoral stem

Classification Name and Reference: Hip Joint Metal/Polymer
Semi-constrained Cemented Prosthesis
§888.3350

Predicate Device Identification

The subject Osteonics® Omnifit®-C Cemented Hip Stems are substantially equivalent to the predicate Osteonics® Omnifit®-C Cemented Hip Stems.

Device Description

The modified Osteonics® Omnifit®-C Cemented Hip Stems have the same design as the predicate Osteonics® Omnifit®-C Cemented Hip Stems, except that the modified components feature a 5mm longer neck.

Intended Use:

The Osteonics® Omnifit®-C Cemented Hip Stems are intended for single-use in patients requiring hemi-hip replacement, bi-polar hip replacement, or total hip replacement. The Osteonics® Omnifit®-C Cemented Hip Stems are intended for cemented applications.

Indications

For use as a bipolar or 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 that indicate a more conservative acetabular procedure and an avoidance of use of bone cement in the acetabulum.
- Salvage of a failed total hip arthroplasty.

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 subject Osteonics® Omnifit®-C Cemented Hip Stems are identical to the predicate Osteonics® Omnifit®-C Cemented Hip Stems except that the subject devices feature a neck length that is 5mm greater. This modification is non-significant, however, because the 5mm gained on the stem side have been compensated for by subtracting 5mm on the femoral head side (i.e., by contraindicating the modified stem for use with +10mm heads).

Performance Data:

No mechanical testing is required to demonstrate the substantial equivalence of the subject device to its predicate version. In effect, 5mm of offset have been shifted from the head side (in the case of the predicate device) to the stem side (in the case of the subject device). Therefore, the most severe predicate device combination remains equivalent to the most severe subject device combination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Terry Sheridan
Regulatory Affairs Specialist
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

SEP 25 1997

Re: K972460
Trade Name: Osteonics® OmniFit®-C Cemented Hip Stems
Regulatory Class: II
Product Code: JDI
Dated: June 30, 1997
Received: July 1, 1997

Dear Ms. Sheridan:

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. 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. 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 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): K972460

Device Name: Osteonics® Omnifit®-C Cemented Hip Stems

Indications For Use:

The Osteonics® Omnifit®-C Cemented Hip Stems are intended for single-use in patients requiring hemi-hip replacement, bi-polar hip replacement, or total hip replacement. The Osteonics® Omnifit®-C Cemented Hip Stems are intended for cemented applications.

Indications

For use as a bipolar or 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 that indicate a more conservative acetabular procedure and an avoidance of use of bone cement in the acetabulum.
- Salvage of a failed total hip arthroplasty.

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972460

(Optional Format 1-2-96)