

**510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Osteonics® Alumina C-Taper Head**

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Osteonics Corporation 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Kate Sutton Regulatory Affairs Specialist
Date of Summary Preparation:	April 15, 1997

Device Identification

Proprietary Name:	Osteonics® Alumina C-Taper Head
Common Name:	Ceramic Femoral Bearing
Classification Name and Reference:	Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented or Nonporous Uncemented Prosthesis 21 CFR §888.3353

Predicate Device Identification

The Osteonics® Alumina C-Taper Head is substantially equivalent to the following competitive and/or Osteonics devices, which have previously been determined substantially equivalent by FDA:

- Osteonics® Omnifit® Ceramic Morse Taper Head
- Osteonics® Zirconia C-Taper Femoral Bearing Head

Device Description

Osteonics® Alumina C-Taper Heads are alumina ceramic femoral bearings that have been designed for assembly, through a taper lock mechanism, to Ti6Al4V alloy stems with the Osteonics

C-Taper trunnion design. The Osteonics® Alumina C-Taper Heads are available in 28mm diameter and 32mm diameter sizes, and in neck extensions of +0mm and +5mm.

The Osteonics® Alumina C-Taper Heads are characterized by the following features:

- A basic spherical design.
- A smooth exterior finish.
- An interior geometry which accommodates any Osteonics stem with a C-Taper trunnion.

These heads differ from the predicate Osteonics® C-Taper Zirconia Ceramic Heads in that they feature alumina instead of zirconia ceramic; however both heads incorporate the identical C-Taper bore design. If the titanium adaptor sleeve of the Osteonics® Alumina Ceramic Bearing Head were excluded, the subject head would be identical in design and material to the predicate head.

Intended Use:

The Osteonics® Alumina C-Taper Heads are single-use devices and may be used with all appropriately selected, legally marketed Osteonics Ti6Al4V femoral stems that incorporate a C-Taper trunnion. Additionally, the Osteonics® Alumina C-Taper Head is intended for use with any appropriately selected, legally marketed Osteonics polyethylene acetabular cup liner and associated metal shell, bipolar or Osteonics all-polyethylene acetabular cup.

Indications:

For use as a Bipolar Hip Replacement:

The indications for the use of the Osteonics® Alumina C-Taper Head, in keeping with those of other legally marketed Osteonics ceramic bearings, 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 in avoidance of the use of bone cement in the acetabulum.
- Salvage of 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 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 substantial equivalence of the Osteonics® Alumina C-Taper Heads to the predicate devices identified above—in terms of intended use, materials, and design features—is based on the following.

Intended Uses:

The Osteonics® Alumina C-Taper Head, like the predicate Osteonics® C-Taper Zirconia Ceramic Heads cited above, is intended for use with any appropriately selected, legally marketed Osteonics polyethylene acetabular cup liner or any Osteonics all-polyethylene acetabular cup.

Materials:

The Osteonics® Alumina C-Taper Head and the predicate Osteonics® Alumina Ceramic Bearing Head and Titanium Adaptor Sleeve Assembly cited above are manufactured from the same materials, exclusive of the titanium adaptor sleeve. Both devices are fabricated from high density, high purity, fine grain Aluminum Oxide (Al_2O_3) ceramic (ASTM F-603).

Design:

The design of the Osteonics® Alumina C-Taper Head is consistent with that of the predicate Osteonics® Alumina Ceramic Bearing Head and Titanium Adaptor Sleeve Assembly and differs only in the following:

- The Osteonics® Alumina C-Taper does not have a titanium adaptor sleeve.

The design of the Osteonics® Alumina C-Taper Head is consistent with that of the predicate Osteonics® C-Taper Zirconia Ceramic Head and differs only in the following:

- The subject device is fabricated from alumina ceramic, whereas the predicate device is fabricated from zirconia ceramic.

None of these design or material differences raise any new questions of safety or effectiveness.

Summary

Based on the similarities presented above, the supporting testing summary, the pre-clinical data incorporated by reference to prior submissions, and the fact that the Osteonics® Alumina C-Taper Heads employ standard sterilization and packaging methods, the substantial equivalence of the Osteonics® Alumina C-Taper Heads to other legally marketed, class II, acetabular femoral head components is demonstrated.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL - 9 1997

Re: K971409
Osteonics® Alumina C-Taper Head
Regulatory Class: II
Product Code: LZO
Dated: April 15, 1997
Received: April 16, 1997

Dear Ms. Sutton:

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 Osteonics® Alumina C-Taper Heads are to be used only with Ti6Al4V alloy hip stems with the C-Taper trunnion design.

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.

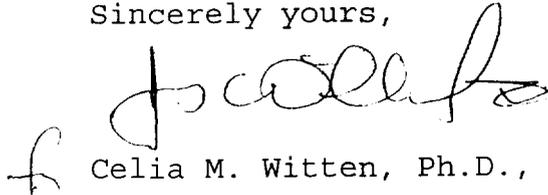
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the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

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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,

A handwritten signature in cursive script, appearing to read "C. Witten".

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): K971409

Device Name: Osteonics® Alumina C-Taper Head

Indications For Use:

The indications for the use of these ceramic bearings, in keeping with those of other legally marketed Osteonics ceramic bearings, 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:

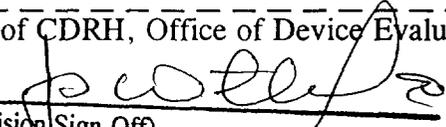
- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and in avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K971409

Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)