JUN 29 1999

K991952

Special 510(k) - Line Extension
Summary of Safety and Effectiveness
for the
Osteonics® Alumina C-Taper Heads and
Osteonics® Trident™ Polyethylene Inserts

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Marybeth Naughton Regulatory Affairs Team Member
Date of Summary Preparation:	June 9, 1999

Device Identification

Proprietary Name:	Osteonics® Alumina C-Taper Head Osteonics® Trident™ Polyethylene Inserts
Common Name:	Ceramic Femoral Bearing Acetabular Insert
Classification Name and Reference:	Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented or Nonporous Uncemented Prosthesis 21 CFR §888.3353/888.3358

Predicate Device Identification

The Osteonics® 36mm Alumina C-Taper Head and mating Osteonics® Trident™ Polyethylene Insert is substantially equivalent to the following Howmedica Osteonics devices, which have previously been determined substantially equivalent by FDA:

- Osteonics® Alumina C-Taper Heads

- Osteonics® Trident Polyethylene Inserts (Osteonics® Generation II Cup Inserts)

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. This line extension to The Osteonics® Alumina C-Taper Heads adds the 36mm diameter size, with neck extensions of +0mm and +5mm. The subject heads are identical in material and design to the predicate heads.

Osteonics® Trident™ Polyethylene Inserts are manufactured from UHMWPE. They are compatible with Trident™ design Acetabular Shells. The subject inserts have an inner diameter of 36mm in order to mate with the subject 36mm alumina 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 alloy femoral stems that incorporate a C-Taper trunnion. Additionally, the Osteonics® 36mm Alumina C-Taper Head is intended for use with any appropriately selected Osteonics® Trident™ Polyethylene Inserts and associated Trident™ Acetabular Shell.

Indications:

- 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.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies in the acetabulum.

Statement of Technological Comparison:

The substantial equivalence of the line extension for Osteonics® Alumina C-Taper Heads and the Osteonics® Trident™ Polyethylene Inserts to the predicate devices identified above—is based on equivalence in intended use, materials, design, indications and contraindications to the Osteonics® Alumina C-Taper Heads (K971409) and the Osteonics® Trident™ Polyethylene Inserts (Osteonics® Generation II Cup Inserts; K983382, K983502).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 1999

Ms. Elizabeth A. Staub
Vice President, Quality Assurance
Regulatory Compliance
Clinical Research
Stryker Howmedica Osteonics
59 Route 17
Allendale, New Jersey 07401

Re: K991952
Trade Name: Line Extension, Osteonics® Alumina C-Taper Heads, Osteonics® Trident™ Polyethylene Inserts
Regulatory Class: II
Product Code: LZO
Dated: June 9, 1999
Received: June 10, 1999

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). 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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): K991952

Device Name: Line Extension - Osteonics® Alumina C-Taper Head, Osteonics® Trident™ Polyethylene Inserts

Indications For Use:

The indications for the use of these ceramic bearing heads and polyethylene inserts are in keeping with those of other legally marketed Osteonics ceramic bearing heads and polyethylene inserts are as follows:

Indications:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previously failed cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies in the acetabulum.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes OR Over-The-Counter Use No

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991952