SEP - 4 2003 K032479

Special 510(k) Summary

Proprietary Name:	Howmedica Osteonics Tibial Tray Screw Hole Plugs
Common Name:	Tibial Tray Screw Hole Plugs
Classification Name and Reference:	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis 21 CFR §888.3560 and Cement Obturator
Proposed Regulatory Class:	Class II
Device Product Code:	87 JWH and LZN
Predicate Proprietary Name:	Osteonics Tibial Tray Screw Hole Plugs
Predicate Regulatory Class:	Class II
Predicate Product Code:	87 JWH and LZN
For Information contact:	Margaret F. Crowe Howmedica Osteonics Corp. 59 Route 17 Allendale, New Jersey 07401-1677 Phone: (201) 831-5580 Fax: (201) 831-6038

Description/Technological Comparison

The subject Tibial Tray Screw Hole Plugs are a line extension to the existing Howmedica Osteonics Tibial Tray Screw Hole plugs found substantially equivalent in premarket notification K970779. The predicate Tibial Tray Screw Hole Plugs are fabricated from low-density polyethylene, and are circular in design. The subject Tibial Tray Screw Hole Plugs are manufactured from ultra high molecular weight polyethylene, and incorporate a tapered design, with a flat bottom with a lip, tapering to a flat top surface.

K032479

Intended Use

The intended use of the new Tibial Tray Screw Hole Plug is the same as that of the predicate device described in premarket notification K970779 – to occlude all tibial tray screw holes not occupied by bone screws. The Tibial Tray Screw Hole Plugs are factory assembled to the tibial tray screw holes. Intraoperatively, the surgeon will remove the plugs from whichever screw holes will be filled with a bone screw. By occluding the tibial tray screw holes, the Tibial Tray Screw Hole Plugs helps prevent intrusion of bone cement onto the tibial tray.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 4 2003

Ms. Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677

Re: K032479
Trade/Device Name: Line Extension – Howmedica Osteonics Tibial Tray Screw Hole Plugs
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis and cement obturator
Regulatory Class: II
Product Code: JWH, LZN
Dated: August 8, 2003
Received: August 12, 2003

Dear Ms. Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

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

Enclosure

510(k) Number (if known): K032479

Device Name: Line Extension – Howmedica Osteonics Tibial Tray Screw Hole Plugs

The subject Tibial Tray Screw Hole Plugs are intended to occlude all tibial tray screw holes not occupied by bone screws. The Tibial Tray Screw Hole Plugs are factory assembled to the tibial tray screw holes. Intraoperatively, the surgeon will remove the plugs from whichever screw holes will be filled with a bone screw. By occluding the tibial tray screw holes, the Tibial Tray Screw Hole Plugs help prevent intrusion of bone cement onto the tibial tray.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use____(Per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032479