AUG 13 1999

K992462

510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Osteonics® Universal Distal Hole Plug

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:	Kate Sutton or Marybeth Naughton Regulatory Affairs Team
Date of Summary Preparation:	July 12, 1999

Device Identification

Proprietary Name:	Osteonics® Universal Distal Hole Plug
Common Name:	Cement Plug
Classification Name and Reference:	Surgical Mesh 21 CFR §878.3300

Predicate Device Identification

The Osteonics® Distal Hole Plug employ features which are substantially equivalent to features of the following Howmedica Osteonics predicate devices, which has been cleared for marketing via the 510(k) process:

- Osteonics® Omnifit® Universal Distal Cement Spacer (K914406)
- Osteonics® Universal Distal Spacer (K894708)

Device Description

The Osteonics® Universal Distal Hole Plug is a single use component which is intended for optional use in cemented arthroplasties of the hip as determined by the physician. The Universal Distal Hole Plugs are manufactured from polymethylmethacrylate (PMMA) or PMMA mixed with Barium Sulfate ($BaSO_4$) and are available in one universal size. The Universal Distal Hole

Plug is cylindrical in shape, has a rounded distal tip, and flares very slightly from the proximal to distal end. The Universal Distal Hole Plug also employs a friction-fit design which secures it in the distal hole of any commercially available Osteonics® cemented hip stem. The Universal Distal Hole Plug is assembled to the hip stem intraoperatively and inserted into the femoral canal.

Intended Use:

The indications for the use of the Osteonics® Universal Distal Hole Plug, in keeping with those of other legally marketed Howmedica Osteonics accessory products for cemented arthroplasty, are as follows:

For cement spacers, mid-shaft restrictors, and Cement-Plugs:

- In cemented hip arthroplasty, when the cement spacer, restrictor and/or plug is thought to be advantageous.

Statement of Technological Comparison:

The Osteonics® Universal Distal Hole Plug is substantially equivalent, in terms of material and basic mechanical function, to the legally marketed versions of the predicate Osteonics® Omnifit® Universal Distal Cement Spacer, manufactured from PMMA mixed with Barium Sulfate, and the predicate Osteonics® Universal Distal Spacer, manufactured from PMMA. The subject and predicate devices are all intended to address similar conditions. However, the predicate devices have fins used for centering the spacer in the femoral canal, whereas the subject device has no fins and serves only to occlude the distal hole of the cemented hip stem in order to prevent cement from intruding into the distal hole. The Universal Distal Hole Plug is available in one universal size because, unlike the predicate device, the subject device does not incorporate fins. Each of the subject and predicate devices is for optional use and is provided in order to accommodate physician preference.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1999

Ms. Elizabeth A. Staub
Vice President
Quality Assurance
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K992462
Trade Name: Osteonics Universal Distal Cement Plug
Regulatory Class: II
Product Code: LZN
Dated: July 21, 1999
Received: July 23, 1999

Dear Ms. Staub:

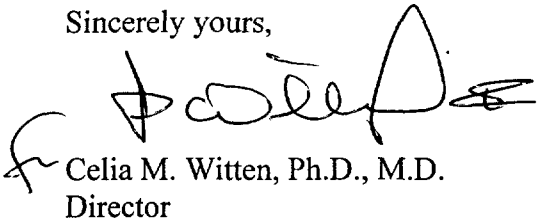
We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 control provisions of the Act. The general control 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,



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): K992462

Device Name: Osteonics® Universal Distal Hole Plug

Indications For Use:

The indications for the use of the Osteonics® Universal Distal Hole Plug, in keeping with those of other legally marketed Osteonics accessory products for cemented arthroplasty, are as follows:

For cement spacers, mid-shaft restrictors, distal plugs, and cement plugs:

- In cemented hip arthroplasty, when the cement spacer, restrictor and/or plug is thought to be advantageous.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992462