WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

K971429

JUL - 9 1997

510(k) Summary

Contact Person: Cristie Manuel
Date Prepared: April 17, 1997

Trade/Common Name:	INTERSEAL® Acetabular Screw Hole Plug
Classification Name:	Hip joint, metal/polymer/metal semi-constrained, porous-coated uncemented prosthesis
Predicate Devices:	INTERSEAL® Apical Hole Plug manufactured by Wright Medical Technology, Inc.; and Opti-Fix Cement Spacer Pod manufactured by Smith and Nephew.

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Description

The INTERSEAL® Acetabular Screw Hole Plug provides an optional filler for INTERSEAL® acetabular shell screw holes to prevent a pathway for wear debris through unused screw holes holes during placement of the acetabular shell without screws. The INTERSEAL® Acetabular Screw Hole Plug is machined from ultra high molecular weight polyethylene (UHMWPE) conforming to ASTM F 648. The one-piece, snap-in design will be offered sterile in a pack of up to four plugs for insertion into the screw holes of the INTERSEAL® Acetabular Cup by the surgeon during implantation.

Indications

This device is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia; 2) inflammatory degenerative joint disease such as rheumatoid arthritis; 3) correction of functional deformity; 4) revision procedures where other treatments or devices have failed; and, 5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Testing Summary

Tensile properties of the EtO-sterilized components and control unsterilized UHMWPE bar stock meet or exceed the minimum requirements of ASTM F 648.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Christie Manuel
Regulatory Affairs Associate
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

JUL - 9 1997

Re: K971429
INTERSEAL® Acetabular Screw Hole Plug
Regulatory Class: II
Product Code: LPH
Dated: April 17, 1997
Received: April 18, 1997

Dear Ms. Manuel:

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

C. Indications for Use of the Device

510(k) Number (if known): 971429

Device Name: INTERSEAL® Acetabular Screw Hole Plugs, Product Line Addition to the INTERSEAL® Acetabular Cup

Indications for Use:

The INTERSEAL® Acetabular Cup is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and,
5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971429

Prescription Use X **Or** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)