AUG -6

Standards Data Form for Abbreviated 510(k)s

510(k) Number: K990666

Standard Organization No: ASTM
Standard Identification No: F1472, F67
CDRH Internal Reference No: 433, 411

Comment: These two ASTM standards are materials' specification only.

Declaration of Conformity Elements:			
Any Adaptations Applied	yes	no	x
Any Requirements Not Applicable	yes	no	x
Any Deviations Applied	yes	no	x
Any Differences in Device Tested and Finished Product	yes	no	x
*Is There a Third Party or Test Lab Involved	yes	no	x

Was there another standard used in the review of this submission? yes no x

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks

K990666

510(k) Summary
Hyaroxyapatite (HA) Coated Reflection® Acetabular Shell
Hydroxyapatite (HA) Coated Reflection InterFit® Shell

Submitter's name:	Smith & Nephew, Inc., Orthopaedic Division
Submitter's address:	1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number:	901/399-5153
Contact person:	Janet Johnson Green
Date summary prepared:	February 26, 1999
Trade or proprietary device name:	HA Coated Reflection Acetabular Shell HA Coated Reflection InterFit Shell
Common or usual name:	Acetabular Shell
Classification name:	Title 21 CFR 888.3358 Hip joint metal/ polymer/ metal, semi-onstrained porous-coated uncemented prosthesis

Device Product Code and Panel Code: 87MEH - Panel: Orthopaedics/87

Substantially Equivalent, Legally Marketed Predicate Devices:
Reflection Acetabular Shell - Smith & Nephew, Inc.
Reflection InterFit Actebular Shell - Smith & Nephew, Inc.
Osteonics® SecurFit™HA Hydroxylapatite Coated Shell
Osteonics® Normalized AD-HA Acetabular Component System
Osteonics® HA Generation II Acetabular component System
Osteonics® Restoration HA Hip Stems
APR Porous HA Hip Stem - Sulzar Orthopedics, Inc.

Subject device description:
The ***Reflection*** acetabular shells are hemispherical in shape. Shells are available with and without holes. Multi-hole shells are designed to accommodate metallic cancellous screws. ***HA Reflection Acetabular Shells*** and ***HA Reflection InterFit Shells*** are used with existing ***Reflection*** UHMWPE liners.

Subject device intended use:
Total hip components are indicated for individuals undergoing primary or revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital eiphysis, fused hip, fracture of the pelveis, and diastrophic variant; congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteoeomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

HA Coated Reflection Acetabular Shells and ***HA Coated Reflection InterFit Acetabular Shells*** are for single use only and are intended for cementless fixation.

Technolocgical Characteristics:
HA Reflection Acetabular Shells and ***HA Reflection InterFit Acetabular Shells*** are similar to legally marketed devices listed above in that all of these devices are indicated for total hip replacement, are manufactured from similar or like materials, and are similar in technological characteristics. Performance characteristics:

Data indicate that ***HA Reflection Acetabular Shells*** and ***HA Reflection InterFit Acetabular Shells*** are substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG -6 1999

Ms. Trude C. McLean
Sr. Regulatory Affairs Specialist
Smith & Nephew, Incorporated
1450 Brooks Road
Memphis, Tennessee 38116

Re: K990666
Trade Name: Hydroxyapatite Reflection® Acetabular Shells
Regulatory Class: II
Product Code: MEH
Dated: May 28, 1999
Received: June 2, 1999

Dear Ms. McLean:

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 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

INDICATIONS STATEMENT

HA Coated Reflection® Acetabular Shell
HA Coated Reflection InterFit® Acetabular Shell

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(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K940666

Prescription Use X
(Per 21 CFR 801.109)