OCT 22 1999

K991026

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

Reflection® Cross-linked UHMWPE Acetabular Components

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the Reflection® Cross-linked UHMWPE Acetabular Components.

Submitted By:	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Date:	March 26, 1999
Contact Person:	Ehab M. Esmail Regulatory Affairs Specialist II
Proprietary Name:	Reflection® Cross-linked UHMWPE Acetabular Components
Common Name:	Polyethylene Acetabular Components
Classification Name and Reference:	21 CFR 888.3350 Prosthesis, Hip, Semi-Constrained, metal/polymer, Cemented – Class II 21 CFR 888.3358 Prosthesis, Hip, Semi-Constrained, metal/polymer, Uncemented – Class II
Device Product Code and Panel Code:	Orthopedics/87/LPH, JDI

I. DEVICE INFORMATION

A. INTENDED USE

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

B. DEVICE DESCRIPTION

The intended use, type of interface, and design features of The Reflection® Cross-linked UHMWPE Acetabular Components are substantially equivalent to the subject identical predicate counterparts fabricated from conventional UHMWPE.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The Reflection® Cross-linked UHMWPE Acetabular Components are substantially equivalent to the subject identical predicate counterpart. The intended use, material, and design features of The Reflection® Cross-linked UHMWPE Acetabular Components are substantially equivalent to predicate competitive devices.

While the Reflection® Cross-linked UHMWPE Acetabular Components are not identical to all of the predicates, any differences that may exist do not significantly affect the safety and effectiveness.

D. WEAR CLAIMS

The following marketing claims will be made for the Reflection® Cross-linked UHMWPE Acetabular Components:

1. Meets all ASTM F648 minimum standards.
2. No free radicals detectable when analyzed by the ESR technique of the final product. (The detection limit is approximately 10^{13} spins/gram).
3. No detectable oxidation as measured by FTIR up to 21 days of accelerated aging at 74°C.
4. 91.9% reduction in volumetric wear rate versus the identical predicate counterpart fabricated from conventional UHMWPE. Testing was performed in a multiaxial hip joint simulator for min. 3.8 million – max. 5.1 million cycles per individual test using a 32mm wrought CoCr head articulating counterface, a 32mm ID, 56mm OD, minimum thickness 7mm liner with the 20 degree overhang design and Hyclone bovine calf serum as a lubricant.

E. SUMMARY OF TECHNOLOGICAL COMPARISON

The intended use, material, type of interface, and design features of The Reflection® Cross-linked UHMWPE Acetabular Components are similar to their predicate component counterparts. The raw material used in manufacturing both the subject and predicate devices are UHMWPE per ASTM F-648. The modification to the manufacturing process of this polyethylene resulted in a higher cross-linked polyethylene. The safety and effectiveness of this cross-linked polyethylene in acetabular applications, as well as the proposed wear claims, are adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1999

Mr. Ehab M. Esmail
Regulatory Affairs Specialist II
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K991026
Trade Name: Reflection Cross-Linked Ultra-High-Molecular-Weight Polyethylene (UHMWPE) Acetabular Components
Regulatory Class: II
Product Codes: LPH and JDI
Dated: July 23, 1999
Received: July 26, 1999

Dear Mr. Esmail:

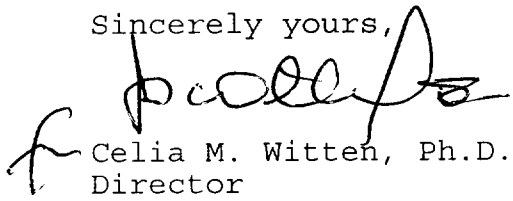
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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

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INDICATIONS STATEMENT

Reflection® Cross-linked UHMWPE Acetabular Components

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(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991026

Prescription Use X
(Per 21 CFR 801.109)