K013658

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510(K) SUMMARY

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.

Submitter's name:	Smith & Nephew, Inc.
Submitter's address:	1450 Brooks Road Memphis, TN 38116
Submitter's telephone number:	901-399-6487
Contact person:	David Henley
Date summary prepared:	November 5, 2001
Trade or proprietary name:	Reflection® Cross-linked UHMWPE Acetabular Components
Common or usual name:	Polyethylene Acetabular Components
Classification name:	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

Substantially Equivalent Legally Marketed Devices

- Reflection® Cross-linked UHMWPE Acetabular Components – Smith & Nephew, Inc.
- Zirconia Ceramic Femoral Heads – Smith & Nephew, Inc.

Device Description:
The intended use, type of interface, and design features of the Reflection® Cross-linked UHMWPE Acetabular Components are identical to Smith and Nephew, Inc. predicate counterparts cleared for market under K002747.

- This Special 510(k) premarket notification is requesting approval for use of Reflection® 10 Mrad Cross-Linked UHMWPE Acetabular Components with zirconia ceramic femoral heads.

Device 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.

Reflection® Cross-linked UHMWPE Acetabular Components are designed for single use only.

Technological Characteristics:
The polyethylene devices that are the subject of this Special 510(k) premarket notification are identical to Smith and Nephew, Inc. predicate device counterparts cleared for market under K002747. Thus, the intended use, material, and design features of Reflection® Cross-linked UHMWPE Acetabular Components are identical to devices approved under K002747. There have been no modifications to the manufacturing process for the Cross-Linked UHMWPE material used to manufacture these devices. The safety and effectiveness for Smith and Nephew's Reflection® Cross-Linked UHMWPE material in acetabular liner/cup applications, as well as the proposed wear claims, are adequately supported by the substantial equivalence information, materials data, and testing results provided in this Special 510(k) premarket notification.

Performance characteristics:
Test data indicate that the Reflection® Cross-linked UHMWPE Acetabular Components meet the requirements of draft *Guidance Document for Testing Acetabular Cup Prostheses,* dated 05-01-95. The subject devices are identical to predicate devices cleared under K002747.

Wear claims:
The following marketing claims will be made for the Reflection® Cross-linked UHMWPE Acetabular Components articulating against zirconia ceramic femoral heads:

1. No detectable wear as measured gravimetrically.

2. Generation of 84% fewer particles compare to conventional, non-irradiated UHMWPE used against CoCr femoral heads.

3. Generation of 79% fewer particles compare to conventional, non-irradiated UHMWPE used against zirconia ceramic femoral heads.

4. Generation of 41% fewer particles compared to Cross-Linked UHMWPE used against CoCr femoral heads.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 5 2001

Mr. David Henley
Senior Clinical/Regulatory Affairs Specialist
Smith + Nephew, Inc.
Orthopaedics Division
1450 Brooks Rd., Memphis, Tennessee 38116

Re: K013658
Trade Name: Reflection Cross-Linked UHMWPE Acetabular Components
Regulation Number: 21 CFR 888.3350 and 888.3358
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis and Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH and JDI
Dated: November 5, 2001
Received: November 6, 2001

Dear Mr. Henley

We have reviewed your Section 510(k) premarket 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) 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

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Indications Statement

Reflection® Cross-linked UHMWPE Acetabular Components

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.

for Mark N Melkerson

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

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