K072817

510(K) SUMMARY

SMITH & NEPHEW ECHELON TITANIUM HIP SYSTEM

MAY 15 2008

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6055
CONTACT PERSON:	Marlon D. Ridley
DATE SUMMARY PREPARED:	January 16, 2008
TRADE OR PROPRIETARY DEVICE NAME:	Echelon Titanium Hip System
COMMON OR USUAL NAME:	Prosthetic Hip Joint System–Porous Femoral Stem
CLASSIFICATION NAME AND REFERENCE:	21 CFR 888.3358 Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis - Class II 21 CFR 888.3350 Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis - Class II 21 CFR 888.3353 Hip Joint Metal/Ceramic/Polymer Semi-Constrained – Class II 21 CFR 878.3300 Surgical Mesh – Class II
PRODUCT CODE AND PANEL CODE:	Orthopaedics 87 / LPH / MBL / MEH / JDI / JDJ

DEVICE INFORMATION:

A. INTENDED USE:

The Echelon Titanium Hip System is indicated for individuals undergoing primary and 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 epiphysis, fused hip, fracture of the pelvis, and dlastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

The Echelon Titanium Hip System is intended for single use only and implanted without bone cement.

B. DEVICE DESCRIPTION:

The body of the Echelon Titanium Hip System femoral stems is similar in shape to the Anthology® Hip Stem as previously cleared under premarket notification K052792. The material, porous coating and surface finish of the Echelon Titanium Hip System femoral stems are identical to the Anthology Hip Stem (K052792). The Echelon Titanium Hip System femoral stems are offered in primary and revision options featuring a 10/12 neck taper for use with the 10/12 Taper Femoral Heads.

C. SUBSTANTIAL EQUIVALENCE INFORMATION:

The substantial equivalence of the Echelon Titanium Hip System is supported by its similarities in design features, overall indications, and material composition to table of legally marketed devices for total hip replacement.

COMPANY	PREDICATE DEVICE NAME	510(K)	CLEARANCE DATE
Smith & Nephew, Inc.	ANTHOLOGY® Hip Stems	K052792	10/07/2005
Wright Medical Technology, Inc.	Profemur Renaissance Total Hip System	K051995	08/22/2005
Ortho Development Corporation	Encompass Cemented Hip Stem and 10/12 Cobalt Chrome Heads	K050637	09/23/2005
Smith & Nephew, Inc.	Global Taper Tapered Hip System	K963509	01/27/1997
Smith & Nephew, Inc.	Hip Joint Prosthesis (Richards Modular Hip System)	K924100	04/02/1993

D. SUMMARY OF TECHNOLOGICAL COMPARISON:

The intended use, design, and materials of the Echelon Titanium Hip System are similar to the legally marketed devices listed above. The Echelon Titanium Hip System components have the same technological characteristics as each of the legally marketed devices listed above as indicated for total hip replacement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2008

Smith & Nephew, Inc.
% Mr. Jason Sells
Project Manager, Regulatory Affairs
1450 Brooks Road
Memphis, TN 38116

Re: K072817
Trade/Device Name: Echelon Titanium Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, MBL, JDI, MEH, JDJ
Dated: May 12, 2008
Received: May 13, 2008

Dear Mr. Sells:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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We are smith&nephew

K072817

Indications for Use

510(k) Number (if known):

Device Name: Echelon Titanium Hip System

Indications for Use:

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Prescription Use		AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)	X		(21 CFR 807 Subpart C)	

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Indications1.doc

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