Summary of Safety and Effectiveness

Smith & Nephew, Inc. LEGION Cobalt Chrome Revision Knee System

Contact Person and Address
Jason Sells
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 E. Brooks Road
Memphis, Tennessee 38116
(901) 399-5520

Date of Summary: March 17, 2006

MAY

Name of Device: LEGION Cobalt Chrome Revision Knee System
Common Name: Knee Prosthesis

Device Description

The LEGION Cobalt Chrome Revision femoral component is a modification of the Revision femoral components cleared via K043440. The subject device is identical in design to the predicate, but the material has been changed from Oxinium, an oxidized zirconium alloy, to cobalt chrome.

Device Classification

21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained knee prosthesis – Class II

Mechanical and Clinical Data

A review of the mechanical and clinical data indicated that the LEGION Cobalt Chrome Revision Knee System is equivalent to devices currently used clinically and is capable of withstanding expected *in vivo* loading without failure.

Intended Use

Revision Knee System components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity levels are compatible with an adequate long-term result; failed osteotomies, unicompartmental replacement, or total knee replacement. The components are designed for use in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent. The Revision Knee components are for single use only and are intended for implantation with bone cement.

Substantial Equivalence Information

The LEGION Cobalt Chrome Revision Knee System components are similar to the following commercially available devices regarding design features, overall indications, and materials:

- Smith & Nephew Revision Knee System (K041106, K043440)
- Zimmer Legacy Constrained Condylar Knee (L-CCK)
- Biomet Oncology Salvage System (OSS)
- Sulzer Orthopedics MOST™ System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 2006

Mr. Jason Sells
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 E. Brooks Road
Memphis, Tennessee 38116

Re: K060742
Trade/Device Name: Legion Cobalt Chrome Revision Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: April 27, 2006
Received: April 28, 2006

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.

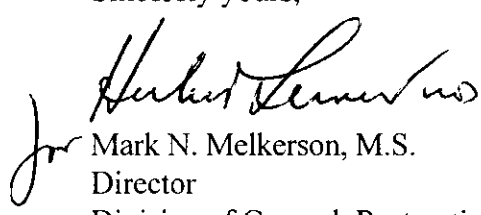
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: LEGION Cobalt Chrome Revision Knee System

Indications for Use:

Revision Knee System components are indicated for:

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity levels are compatible with an adequate long-term result.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. The constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

The Revision Knee components are for single use only and are intended for implantation with bone cement.

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

510(k) Number K060742