K071471 (pg 1/2)

SEP 10 2007

510(k) Summary of Safety and Effectiveness

Proprietary Name:	Corin Adaptor Sleeve
Common Name:	Adaptor Sleeve
Classification Name and Reference:	21 CFR §888.3360: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.
Proposed Regulatory Class:	Class II
Product Codes:	KWL: prosthesis, hip, hemi-, femoral, metal
For Information contact:	Karen Ariemma, Senior Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5718 Fax: (201) 831-6038
Date Prepared:	May 4, 2007

Description:

The Corin Adapter Sleeve is a tapered sleeve component with a female V40™ taper to provide locking with a Howmedica Osteonics' femoral stem with a V40™ taper. In addition, the sleeve has a tapered male exterior surface that provides locking with a Corin Unipolar Modular Head. The Corin Adapter Sleeve is fabricated from Ti-6Al-4V alloy per ASTM F-136.

Indications:

The Corin Adaptor Sleeve is indicated for use with a Corin Unipolar Modular Head and a Howmedica Osteonics femoral hip stem with a V40™ trunnion in partial hip replacement procedures for patients suffering from pain and disability due to osteoarthritis, rheumatoid arthritis, avascular necrosis of the femoral head, femoral neck fracture and abnormalities where the major pathology affects the femoral head, the acetabular cavity is normal and acetabular replacement is either undesirable or not required.

Substantial Equivalence:

The Corin Adaptor Sleeve is substantially equivalent to other commercially available adaptor sleeves in regards to intended use, design, materials, and operational principles. The following devices are examples of predicate systems: the V40™/C-Taper Adaptor Sleeve and the Unitrax Unipolar System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 2007

Howmedica Osteonics Corp
% Ms. Karen Ariemma
Senior Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, NJ 07430

Re: K071471
Trade/Device Name: Corin Adaptor Sleeve
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prothesis
Regulatory Class: Class II
Product Code: KWL
Dated: August 29, 2007
Received: August 30, 2007

Dear Ms. Ariemma:

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.

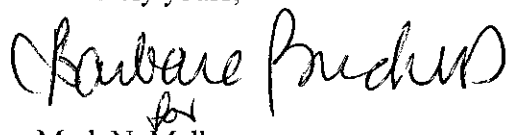
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

Indications for Use

510(k) Number (if known): K071471 (pg 1/1)

Device Name: Corin Adaptor Sleeve

Indications for Use:

The Corin Adaptor Sleeve is indicated for use with a Corin Unipolar Modular Head and a Howmedica Osteonics femoral hip stem with a V40™ trunnion in partial hip replacement procedures for patients suffering from pain and disability due to osteoarthritis, rheumatoid arthritis, avascular necrosis of the femoral head, femoral neck fracture and abnormalities where the major pathology affects the femoral head, the acetabular cavity is normal and acetabular replacement is either undesirable or not required.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

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

510(k) Number K071471