APR - 3 2007

K063791

3. 510(K) SUMMARY

1. Applicant/Sponsor: Corin USA
10500 University Center Drive
Suite 190
Tampa, Florida 33612
Establishment Registration No.: 1056629

2. Contact Person: Kathy K. Trier, Ph.D.
Director Clinical and Regulatory Affairs
Corin USA
813-977-4469
kathy.trier@coringroup.com

3. Proprietary Name: Corin Unipolar Modular Head

4. Common Name: Unipolar Modular Head

5. Classification Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21CFR 888.3360)

6. Legally Marketed Devices to which Substantial Equivalence is claimed:
   a. Johnson & Johnson ULTIMA Unipolar Modular Heads (K940190)
   b. Howmedica Unitrax Unipolar System (K902365)
   c. Howmedica Osteonics Unitrax C-Taper Neck Adjustment Sleeve (K992570)
   d. Osteonics Ion Implanted Femoral Bearings (K910988)

7. Device Description:

   The Corin Unipolar Modular Head is a polished, truncated sphere with a high tolerance internal female taper. It is designed to be used with a number of femoral hip stem designs which incorporate a compatible male taper. The Corin Unipolar Modular Head is manufactured from Cobalt-Chrome alloy conforming to ASTM F75 and is available in diameters ranging from 40-56mm and a variety of offsets.

8. Intended Use / Indications:

   The Corin Unipolar Modular Head is indicated for hemi-arthroplasty in cemented and uncemented primary or revision femoral stem applications whose indications include procedures for patients suffering 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.

9. Summary of Technologies/Substantial Equivalence:

   The Corin Unipolar Modular Heads have the same intended use and indications and are manufactured from the same materials as the predicate Johnson & Johnson ULTIMA Unipolar Heads and Howmedica Unitrax Unipolar System. The range of diameters available falls within the range cleared for the ULTIMA and Unitrax devices. The range of offsets available falls within the range cleared for the Unitrax devices. The Corin Unipolar Modular Heads have an internal taper that is substantially equivalent to the internal taper of the Howmedica Osteonics (now Stryker Orthopaedics) Unitrax C-Taper Neck Adjustment Sleeves and the Osteonics (now Stryker Orthopaedics) Ion Implanted Femoral Bearings. Based on these similarities, Corin believes that the Unipolar Modular Heads are substantially equivalent to these predicate devices.

10. Non-Clinical Testing:

    Non-clinical testing and analysis included Finite Element Analysis, mechanical fatigue testing, mechanical axial pull-off and dimensional comparison. The results of this testing and analysis show that the Corin Unipolar Modular Head is expected to be safe and effective for the proposed indications and is substantially equivalent to the predicate devices.

11. Clinical Testing:

    Clinical testing was not necessary to determine substantial equivalence between the Corin Unipolar Modular Head and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Corin USA
c/o Kathy K. Trier, Ph.D.
Director, Clinical and Regulatory Affairs
10500 University Center Drive
Suite 190
Tampa, Florida 33612

Re: K063791
Trade/Device Name: Corin Unipolar Modular Head
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWL
Dated: March 13, 2007
Received: March 15, 2007

Dear Dr. Trier:

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.

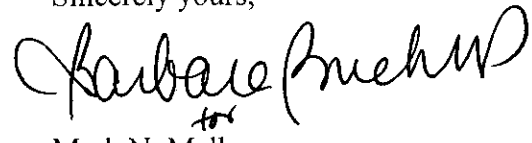
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 or at its 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

2. INDICATIONS FOR USE

510(k) Number (if known): K063791

Device Name: Corin Unipolar Modular Head

Indications for Use:

The Corin Unipolar Modular Head is indicated for hemi-arthroplasty in cemented and uncemented primary or revision femoral stem applications whose indications include procedures for patients suffering 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 (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucheit

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

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