APR 15 2010

3. 510(K) SUMMARY

1. Applicant/Sponsor:	Corin USA 10500 University Center Drive Suite 190 Tampa, Florida 33612 Establishment Registration No.:
2. Contact Person:	Ashlea Bowen Regulatory Affairs Associate Corin USA 813-977-4469 ashlea.bowen@coringroup.com
3. Date of Preparation:	April 15, 2010
4. Proprietary Name:	Cormet Cementless Resurfacing Femoral Head
5. Common Name:	Hemi hip resurfacing femoral component
6. Classification Name:	Hip joint femoral (hemi-hip) metallic resurfacing prosthesis (21CFR 888.3400)

7. Legally Marketed Devices to which Substantial Equivalence is claimed:
   a. Cormet 2000 Hemi Hip Metallic Resurfacing Prosthesis (K994153)
   b. ReCap® HA Press-Fit Femoral Resurfacing Head (K071053)

8. Device Description:

The Cormet Cementless Resurfacing Femoral Head is a femoral component manufactured from cast cobalt-chromium-molybdenum (Co-Cr-Mo) alloy complying with the requirements of ASTM F75 and ISO 5832-4. It is designed to replace the outer surface of the natural femoral head for hemi hip arthroplasty and articulates against the natural acetabulum. The component has a central stem and three internal splines to provide anti-rotational stability. The inner, bone contacting surfaces of the component have coatings of plasma sprayed titanium and hydroxyapatite for cementless fixation. The Cormet Cementless Resurfacing Femoral Head is not approved for use with an acetabular component in the US.

9. Intended Use / Indications:

The Cormet Cementless Resurfacing Femoral Head is indicated for hemi hip resurfacing arthroplasty in patients with non-inflammatory degenerative joint disease, including osteo and rheumatoid arthritis, post traumatic disease and avascular necrosis.

It is indicated for relief of pain and disability, and to restore hip function within patients who have radiographic evidence of good bone stock in the femoral head and acetabulum, the bearing surface and supportive bone structure of the acetabulum being normal.

It is intended for patients having deformities of the hip that do not lend themselves to conventional total hip replacement such as:

- previously failed femoral osteotomy,
- early deformities of the proximal end of the femur.

The Cormet Cementless Resurfacing Femoral Head is indicated for cementless use only

10. Summary of Technologies/Substantial Equivalence:

The Cormet Cementless Resurfacing Femoral Head is geometrically identical to and has identical bearing surface characteristics as the predicate Cormet 2000 Hemi Hip Resurfacing device (K994153) with the addition of 4 more sizes included within the range of the currently cleared device. It has the same indications for use, is similar in design, and manufactured from the same materials, surface finishing, and processing as the predicate device the Biomet ReCap® HA Press-Fit Femoral Resurfacing Head (K071053). Based on these similarities, Corin believes that the Cormet Cementless Resurfacing Femoral Head is substantially equivalent to the predicate devices.

11. Non-Clinical Testing:

Non-clinical testing submitted to support a determination of substantial equivalence was based on coating characterization. The coating applied to the Cormet Cementless Resurfacing Femoral Head consisting of plasma sprayed titanium and hydroxyapatite was characterized and cleared under K083312 (Corin MiniHip Stem).

No additional bench testing was required since the cemented version of the device is a legally marketed predicate device.

12. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Cormet Cementless Resurfacing Femoral Head and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Corin USA
% Ms. Ashlea Bowen
Regulatory Affairs Associate
10500 University Center Drive, Suite 190
Tampa, Florida 33612

APR 1 5 2010

Re: K092198
Trade/Device Name: Cormet Cementless Resurfacing Femoral Head
Regulation Number: 21 CFR 888.3400
Regulation Name: Hip joint metal femoral (hemi-hip) metallic resurfacing prosthesis
Regulatory Class: II
Product Code: KXA
Dated: January 28, 2010
Received: January 29, 2010

Dear Ms. Bowen:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K092198

Device Name: Cormet Cementless Resurfacing Femoral Head

Indications for Use:

The Cormet Cementless Resurfacing Femoral Head is indicated for hemi hip resurfacing arthroplasty in patients with non-inflammatory degenerative joint disease, including osteo and rheumatoid arthritis, post traumatic disease and avascular necrosis.

It is indicated for relief of pain and disability, and to restore hip function within patients who have radiographic evidence of good bone stock in the femoral head and acetabulum, the bearing surface and supportive bone structure of the acetabulum being normal.

It is intended for patients having deformities of the hip that do not lend themselves to conventional total hip replacement such as:

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The Cormet Cementless Resurfacing Femoral Head is indicated for cementless use only.

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)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K092198