FEB 25 2000

510(k) SUMMARY

K994153

Name of Company: Corin Medical
The Corinium Centre
Cirencester
Gloucestershire
GL7 1YJ
England

Name of Device: The Cormet 2000 Hemi Hip Metallic Resurfacing Prostheses.

Device Description:

These devices are intended for use with hip joints in which the concentricity of the bearing surface, and supportive bone structure of the acetabulum, is essentially normal.

Selection of the implant from the available range of sizes provides reasonably precise articulation.

The devices are used to resurface the head of the femur, and so reinstate function of the hip joint following the degenerative effects of osteo and rheumatoid arthritis, post traumatic disease and avascular necrosis.

The Cormet 2000 Hemi Hip Metallic Resurfacing Prostheses consists of 5 sizes ranging from 40 to 56mm diameter in 4mm increments.

These devices are intended for use with bone cement and have been designed to replace only a small portion of the of the worn femoral head. Stable and immobile fixation of the implant provides stress bearing contact at the bone / prosthetic interface.

The Cormet 2000 Hemi Hip Metallic Resurfacing Prostheses are manufactured from Cobalt Chromium Molybdenum alloy in accordance with ISO 5832-4/BS 7252/4 : 1997 – 'Specification for cobalt-chromium-molybdenum casting alloy', and is cast in accordance with BS 7254 Pt.5 1990-'Specification for production of castings made of cobalt-chromium-molybdenum alloy'.

The Cormet 2000 Hemi Hip Metallic Resurfacing Prostheses are manufactured in accordance with BS EN 12010 : 1998 – 'Non-active Surgical Implants - Joint Replacement Implants - Particular Requirements', BS EN ISO 14630:1998 – General requirements for non-active surgical implants and BS EN 12563:1999 Non active surgical implants – Joint replacements – Specific requirements for hip joint replacement implants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2000

Mr. Craig Corrance
President
Corin U.S.A.
10500 University Center Drive
Suite 190
Tampa, Florida 33612

Re: K994153
Trade Name: Cormet 2000 Hemi Hip Metallic Resurfacing Prostheses
Regulatory Class: II
Product Code: KXA
Dated: December 8, 1999
Received: December 8, 1999

Dear Mr. Corrance:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K994153

Device Name: Comet 2000 Hemi Hip Resurfacing Prosthesis

Indications For Use:

Relief of pain and disability, and restoration of 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.

This prosthesis is also intended for patients having deformities of the hip that do not lend themselves to conventional total hip replacement such as previously failed femoral osteotomy, previous fracture, or early deformities of the proximal end of the femur. These make it anatomically impossible to use a conventional femoral component. As above the acetabulum should be essentially normal.

(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 Devices
510(k) Number K994153

Prescription Use 4/2 OR Over-The-Counter Use /
(Per 21 CFR 801.109)

(Optional Format 1-2-96)