

NOV 23 1999

K 992235

510(k) SUMMARY

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

Name of Device: Zyranox Zirconia Ceramic Modular Heads

Device Description:

A Modular Femoral Head, manufactured from high purity 3 mol% Ytria Stabilized Zirconia Polycrystals (Y-TZP), used in total hip replacement surgery.

These Zirconia Ceramic Modular Heads are available in standard Corin trunnion and Eurocone trunnion options. The devices are available in short, standard and long neck and 28mm and 32mm outside diameters.

The bore of the Modular Head is designed so as to ensure compatibility with the cone (trunnion) of the Femoral Stem, and hence locking of the components in situ.

The Corin Medical Zirconia ceramic modular heads incorporate a female trunnion (taper). The modular head is applied to the male trunnion of a Corin Medical femoral stem.

The Zirconia ceramic modular heads are designed to articulate with ultra high molecular weight polyethylene (UHMWPE) acetabular cups or acetabular cup liners to reinstate function following the degenerative effects of osteo or rheumatoid arthritis, post-trauma disease effects, avascular necrosis and septic or aseptic total hip revision.

Zirconia ceramic modular heads offer an ultra smooth surface in order to decrease torque and reduce stresses normally associated with the articulation of cobalt chromium alloy femoral heads with ultra high molecular weight polyethylene (UHMWPE) acetabular components.

Zirconia ceramic modular heads are more resistant to third body wear from cement particles than cobalt chromium alloy modular heads. This, in conjunction with their low friction and decreased torque, significantly reduces polyethylene wear related total hip prostheses problems such as osteolysis.

The use of zirconia ceramic modular heads also eliminates the release of metallic corrosion particulates into the joint space, which can be found when cobalt chromium alloy heads are mounted onto cobalt chromium alloy femoral stems. These ceramic modular heads are designed for use with cobalt chromium alloy femoral hip stems manufactured by Corin Medical.

Sub-contract manufacture of Corin Medical's Zirconia Ceramic Modular Heads is performed by Morgan Matroc Ltd, St Peter's Road, Rugby, Warwickshire, CV21 3QR, England.

Morgan Matroc Ltd's master file held by the FDA is reference number MAF-343.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 23 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K992235
Trade Name: Zyranox™ Zirconia Ceramic Femoral Heads
Regulatory Class: II
Product Code: LZO
Dated: September 15, 1999
Received: September 24, 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 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 (Pre-market 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 pre-market 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.

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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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


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): K992235

Device Name: Zyranox Zirconia Ceramic Femoral Heads

INDICATIONS FOR USE

The Zirconia Ceramic Modular Heads are used in combination with femoral hip stems and ultra high molecular weight polyethylene (UHMWPE) acetabular cups or acetabular cup liners to reinstate function following the degenerative effects of osteo or rheumatoid arthritis, post-trauma disease effects, avascular necrosis and septic or aseptic total hip revision.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

NRO for

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992235

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No