FEB 1 1 2005 K042992

510(k) Summary

Name of Sponsor:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Est. Reg. No. 1818910

510(k) Contact:

Nancy S. Friddle
Senior Regulatory Associate
Phone: (574) 371-4923
FAX: (574) 371-4987

Trade Name:

Corail AMT™ Hip Prosthesis

Common Name:

Total Hip Prosthesis

Device Classification And Product Code:

Class II
LZO; 21 CFR 888.3353; Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

Class III
KWA; 21 CFR 888.3330; Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

Substantially Equivalent Device:

HA Coating
DePuy Corail® K953111
Hip stem
DePuy Titan™ K001991
(Marketed by name Summit™)

Device Descriptions:

The Corail AMT Hip is a tapered stem available both collarless and collared. This hip stem is manufactured from F-136 titanium (Ti-6Al-4V) and has a layer of hydroxyapatite (HA) coating applied. The Corail AMT Hip is available in standard offset, lateralized high offset and a Coxa vara lateralized offset. The standard offset

510(k) Summary (continued)

stems, collared and collarless, are available in 11 sizes (Size 8 to Size 20). The lateralized high offset and the lateralized Coxa vara high offset are available in 8 sizes (Size 9 to Size 16).

Intended use:

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Indications for use:

Total hip replacement is indicated in the following conditions:

1. Severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The non-porous Corail AMT Hip Stem is indicated for cementless use only.

Substantial equivalence:

The Corail AMT Hip Prosthesis has the same intended use, is made from the same material and has a similar design as the predicate devices and is therefore substantially equivalent.

No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for femoral hip stems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2005

Ms. Nancy S. Friddle
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
P.O Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K042992
Trade/Device Name: Corail AMT™ Hip Prosthesis
Regulation Number: 21 CFR 888.3330 and 21 CFR 888.3353
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis and Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: III
Product Code: KWA, LZO, LWJ, and MEH
Dated: December 30, 2004
Received: January 3, 2005

Dear Ms. Friddle:

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.

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Celia Witten, Ph.D., M.D.
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): K042992

Device Name: **Corail AMT™ Hip Prosthesis**

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

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The non-porous Corail AMT Hip Stem is indicated for cementless use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Mark N Milhous

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K042992