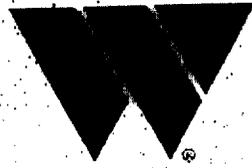


K973296



WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

NOV 24 1997

Contact Person: Kim Tompkins
Date: November 19, 1997

510(k) Summary

Trade/Proprietary Name: Cemented EXTEND™ Hip Stem
Common Name: Femoral Hip Stem
Classification: Class II
Predicate Device: EXTEND™ Hip System, Wright Medical Technology, Inc.

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR §807.92.

Description/Intended Use

The Cemented EXTEND™ Hip Stem is a monolithic design femoral component. The device is manufactured from cast cobalt chrome alloy (ASTM F-75). The stem is available straight with standard or reduced flare, or bowed with a calcar platform. It is intended for use with Wright Medical Technology, Inc. cobalt chrome alloy or alumina ceramic femoral heads. It is designed for use with bone cement.

The Cemented EXTEND™ Hip Stem in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- 1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- 2) inflammatory degenerative joint disease such as rheumatoid arthritis;
- 3) correction of functional deformity;
- 4) revision procedures where other treatments or devices have failed; and,
- 5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Testing

The EXTEND™ Hip System demonstrates acceptable fatigue strength.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kim Tompkins
Director, Clinical and Regulatory Affairs
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

NOV 24 1997

Re: K973296
Trade Name: Cemented EXTEND™ Hip Stem
Regulatory Class: II
Product Codes: JDI and LZO
Dated: August 29, 1997
Received: September 2, 1997

Dear Ms. Tompkins:

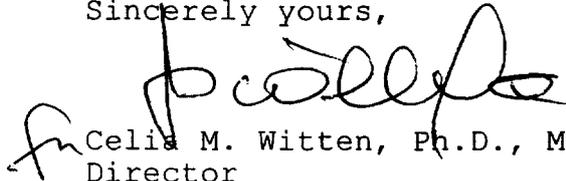
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

C. Indications for Use of the Device

510(k) Number (if known): K973296

Device Name: Cemented EXTEND™ Hip Stem

Indications for Use:

In total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

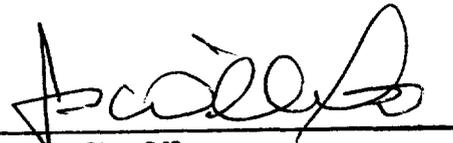
- 1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- 2) inflammatory degenerative joint disease such as rheumatoid arthritis;
- 3) correction of functional deformity;
- 4) revision procedures where other treatments or devices have failed; and,
- 5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

This device is for cemented use only.

(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 K973296

Prescription Use X
(Per 21 CFR 801.109)

Or

Over-the-Counter Use

(Optional Format 1-2-96)