K062960

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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

DEC - 1 2006

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the CONSERVE® Femoral Resurfacing Component.

Submitted By:	Wright Medical Technology, Inc.
Date:	September 28, 2006
Contact Person:	Theresa Leister
	Regulatory Affairs Specialist II
Proprietary Name:	CONSERVE® Femoral Resurfacing Component
Common Name:	Hemi-resurfacing femoral component
	Classification Name and Reference: 21 CFR 888.3400 Hip joint femoral (hemi-hip) metallic resurfacing prosthesis – Class II
Device Product Code and Panel Code:	Orthopedics/87/ KXA

DEVICE INFORMATION

A. INTENDED USE

The CONSERVE® Femoral Resurfacing Component is indicated for use in hemi resurfacing for reduction or relief of pain and/or improved hip function in skeletally mature patients with non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia.

The CONSERVE® Femoral Resurfacing Component is indicated for cemented use only.

B. DEVICE DESCRIPTION

The design features of the CONSERVE® Femoral Resurfacing Component are summarized below:

- Manufactured from Cobalt Chrome Alloy
- 11 Sizes in 2mm increments

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The indications for use and design of the CONSERVE® Femoral Resurfacing Component are identical to Orthomet Resurfacing Femoral Component. The materials of the CONSERVE® Femoral Resurfacing Component are substantially equivalent to those of the predicate device. The fundamental scientific technology of the modified device has not changed relative to the predicate device. The safety and effectiveness of the CONSERVE® Femoral Resurfacing Component are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Wright Medical Technology, Inc.
% Ms. Theresa Leister
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

DEC - 1 2006

Re: K062960
Trade Name: CONSERVE® Femoral Resurfacing Component
Regulation Number: 21 CFR 888.3400
Regulation Name: Hip joint femoral (hemi-hip) metallic resurfacing prosthesis
Regulatory Class: Class II
Product Code: KXA
Dated: November 2, 2006
Received: November 3, 2006

Dear Ms. Leister:

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.

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); 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

K062960

Indications for Use

510(k) Number (if known):

Device Name: CONSERVE® Femoral Resurfacing Component

Indications For Use:

The CONSERVE® Femoral Resurfacing Component is indicated for use in hemi resurfacing for reduction or relief of pain and/or improved hip function in skeletally mature patients with non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia.

The CONSERVE® Femoral Resurfacing Component is indicated for cemented use only.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ruehl for MAM

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K062960