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AUG 19 2005

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

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® Total Femoral Head.

Submitted By:	Wright Medical Technology, Inc.
Date:	August 3, 2005
Contact Person:	Theresa Leister Regulatory Affairs Specialist
Proprietary Name:	CONSERVE® Total Femoral Head
Common Name:	Femoral Head
Classification Name and Reference:	21 CFR 888.3320 Hip joint metal/ metal semi-constrained, with a cemented acetabular component prosthesis – Class III 21 CFR 888.3330 Hip joint metal/ metal semi-constrained, with an uncemented acetabular component prosthesis – Class III
Device Product Code and Panel Code:	Orthopedics/87/JDL Orthopedics/87/KWA

DEVICE INFORMATION

A. INTENDED USE

The CONSERVE® Total Femoral Head is indicated 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; and,
4. revision procedures where other treatments or devices have failed

The CONSERVE® Total Femoral Head is intended for single patient use only.

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B. DEVICE DESCRIPTION

Design Features

The design features of the CONSERVE® Total Femoral Head are summarized below:

- Manufactured from wrought cobalt-chromium-molybdenum
- The articulating surface of the implants will be superfinished
- Available sizes: 36mm, 38mm, 40mm, 42mm, 44mm, 46mm, 48mm, 50mm, 52mm, 54mm, 56mm
- The taper connection is identical to previously cleared taper connections and is intended to be used with our existing femoral stems manufactured with WMT12/14 taper.

Wear Claims

The following marketing claims will be made for the CONSERVE® Total Femoral Head:

- The articulation of the CONSERVE® Total Femoral Head Bearing has an average of 10 times lower volumetric run-in wear rate than the currently available Metal TRANSCEND® Femoral Head Bearings.*
- The articulation of the CONSERVE® Total Femoral Head Bearing has an average of 3.2 times lower cumulative volumetric wear than the currently available Metal TRANSCEND® Femoral Head Bearings.*

*Wear Test Information

(a) The CONSERVE® Total Femoral Head and the Metal TRANSCEND® Femoral Head are manufactured by Wright Medical Technology, Inc.
(b) The test device was the CONSERVE® Total Femoral Head and the control device was the Metal TRANSCEND® Femoral Head
(c) Both the test and control devices were 54mm diameter femoral heads.
(d) The articulating surface of both the test and control device was mirror finished.
(e) The hip simulators used were orbital bearing hip wear test machines manufactured by Shore Western Manufacturing, Inc.
(f) Both the test and control devices were tested for 5 million cycles.
(g) The material of the device was a CoCr alloy and the bearing size was 54mm.
(h) The lubricant used was 90% alpha calf serum with 0.2% sodium azide, 20mM EDTA and distilled water.
(i) The average amount of volumetric wear at 5 million cycles for the test device was 1.02mm^3 less than that of the control device.
(j) Both the test and control devices were sterilized.
(k) The results of in vitro hip wear simulator tests have not been shown to quantitatively predict clinical wear performance.

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C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use and type of interface of the CONSERVE® Total Femoral Head are identical to the Metal TRANSCEND® Femoral Heads (Larger Sizes). The design features and material are substantially equivalent to the Metal TRANSCEND® Femoral Heads (Larger Sizes). The safety and effectiveness of this device are adequately supported by the substantial equivalence information, materials data, and testing results, provided within the Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 2005

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

Re: K051348
Trade/Device Name: NSERVE® Total Femoral Head
Regulation Number: 21CFR 888.3320, 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with a cemented acetabular component prosthesis, Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: JDL, KWA
Dated: August 1, 2005
Received: August 2, 2005

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) 276-0210. 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
Acting 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):

Device Name: CONSERVE® Total Femoral Head

Indications For Use:

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2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

The CONSERVE® Total Femoral Head is intended for single patient 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K051348