K041425

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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® Plus Revision Shell and CONSERVE® Plus Thick Shell.

Submitted By:	Wright Medical Technology, Inc.
Date:	May 27, 2004
Contact Person:	Katie Logerot Regulatory Affairs Specialist II
Proprietary Name:	CONSERVE® Plus Revision Shell and CONSERVE® Plus Thick Shell
Common Name:	Acetabular Shell
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® Plus Revision Shell and CONSERVE® Plus Thick Shell are 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® Plus Revision Shell and CONSERVE® Plus Thick Shell are intended for single patient use only.

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B. DEVICE DESCRIPTION

The design features of the CONSERVE® Plus Revision Shell are summarized below:

- Manufactured from cast cobalt-chromium-molybdenum
- Porous coated with CoCrMo sintered beads
- The articulating surface of the implants will be superfinished
- Offered in inner diameters ranging from 36mm-56mm
- Increased eccentricity and offset and screw holes
- Fins for enhanced fixation

The design features of the CONSERVE® Plus Thick Shell are summarized below:

- Manufactured from cast cobalt-chromium-molybdenum
- Porous coated with CoCrMo sintered beads
- The articulating surface of the implants will be superfinished
- Offered in inner diameters ranging from 36mm-56mm
- Minimum wall thickness: 5.5mm

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, and type of interface of the CONSERVE® Plus Revision Shell and CONSERVE® Plus Thick Shell are identical to the CONSERVE® Plus Spiked Shell. The design features are substantially equivalent to the CONSERVE® Plus Spiked Shell. The safety and effectiveness of this device are adequately supported by the substantial equivalence information, materials data, and testing results, provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 5 2004

Ms. Katie Logerot
Regulatory Affairs Specialist II
Wright Medical Technology, Inc.
5677 Airline Road,
Arlington, Tennessee 38002

Re: K041425
Trade/Device Name: CONSERVE® Plus Revision Shell and CONSERVE® Plus Thick Shell
Regulation Number: 21 CFR 888.3320 and 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis and Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA and JDL
Dated: May 27, 2004
Received: May 28, 2004

Dear Ms. Logerot:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

K041425

Indications for Use

510(k) Number (if known):

Device Name: CONSERVE® Plus Revision Shell and CONSERVE® Plus Thick Shell

Indications For Use:

The CONSERVE® Plus Revision Shell and CONSERVE® Plus Thick Shell are 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;
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4. revision procedures where other treatments or devices have failed

The CONSERVE® Plus Revision Shell and CONSERVE® Plus Thick Shell are intended for single patient 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)

for Mark N Milhous

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

510(k) Number K041425