K031963 p. 1/2

OCT 3 1 2003

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 Spiked Shell and CONSERVE® Total 56mm Femoral Head.

Submitted By:	Wright Medical Technology, Inc.
Date:	June 23, 2003
Contact Person:	Katie Logerot Regulatory Affairs Associate
Proprietary Name:	CONSERVE® Plus Spiked Shell and CONSERVE® Total 56mm Femoral Head
Common Name:	Spiked Acetabular Shell and 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® Plus Spiked Shells and CONSERVE® Total 56mm Femoral Head 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

headquarters
Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002 **901.867.9971** phone **www.wmt.com**
International subsidiaries
011.32.2.378.3905 Belgium 905.826.1600 Canada 011.33.1.45.13.24.40 France 011.49.4161.745130 Germany
011.39.0250.678.227 Italy 011.81.3.3538.0474 Japan 011.44.1483.721.404 UK

K031963 p.2/2

The CONSERVE® Plus Spiked Shells and CONSERVE® Total 56mm Femoral Head are intended for single patient use only.

B. DEVICE DESCRIPTION

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

- Manufactured from cast cobalt-chromium-molybdenum conforming to ASTM F75
- Porous coated with CoCrMo (ASTM F75) Sintered beads
- Available sizes: 36mm-56mm ID; available in two shell thicknesses – 3.5mm and 4.5mm
- The articulating surface of the implants will be superfinished to insure form tolerance and a fine surface finish
- A one-piece acetabular shell allows the surgeon to reconstruct the acetabulum while removing very little bone to accommodate a larger Femoral Head
- Spikes are added to the outer surface to enhance fixation

The design features of the CONSERVE® Total 56mm Femoral Head are summarized below:

- Manufactured from cast cobalt-chromium-molybdenum conforming to ASTM F75
- Available size: 56mm
- Available neck lengths: -3.5, 0, +3.5
- The articulating surface of the implants will be superfinished to insure form tolerance and a fine surface finish
- The taper connection for the CONSERVE® Total 56mm Femoral Head will be identical to the Metal TRANSCEND® Femoral Heads Larger Sizes and is intended to be used with our existing femoral stems manufactured with WMT12/14 taper.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, and type of interface of the CONSERVE® Plus Spiked Shells are identical to the Metal TRANSCEND® Articulation Monoblock Shell. The design features are identical with the exception of additional spikes, a thinner wall, and a larger size offering. The CONSERVE® Total 56mm Femoral Head is a size addition to the Metal TRANSCEND® Femoral Head (Larger Sizes). The design features of the CONSERVE® Total 56mm Femoral Head are identical to the design features of the Metal TRANSCEND® Femoral Head (Larger Sizes). The safety and effectiveness of this device are adequately supported by the substantial equivalence information, materials data, testing results, and clinical data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2003

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

Re: K031963
Trade/Device Name: CONSERVE® Plus Spiked Shell and CONSERVE® Total 56mm Femoral Head
Regulation Number: 21 CFR 888.3320 and 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: September 30, 2003
Received: October 1, 2003

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.

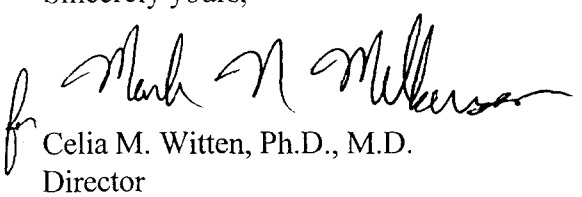
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

K031963

WRIGHT.
TM

CONSERVE® Plus Spiked Shell and CONSERVE® Total 56mm Femoral Head

INDICATIONS STATEMENT

The CONSERVE® Plus Spiked Shells and CONSERVE® Total 56mm Femoral Head 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 Spiked Shells and CONSERVE® Total 56mm Femoral Head are intended for single patient 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 _____

Prescription Use ____ OR Over-The Counter Use ____
(Per21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhern

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

510(k) Number K031963

headquarters
Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002 **901.867.9971** phone **www.wmt.com**

international subsidiaries
011.32.2.378.3905 Belgium **905.826.1600** Canada **011.33.1.45.13.24.40** France **011.49.4161.745130** Germany
011.39.0250.678.227 Italy **011.81.3.3538.0474** Japan **011.44.1483.721.404** UK