APR 18 2006

K060356

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 QUADRA-FIX™ Acetabular Shell.

Submitted By:	Wright Medical Technology, Inc.
Date:	March 14, 2006
Contact Person:	Matt Paul Regulatory Affairs Specialist
Proprietary Name:	CONSERVE® PLUS QUADRA-FIX™ Acetabular Shell
Common Name:	Acetabular Shell
Classification Name and Reference:	21 CFR 888.3330 Hip joint metal/ metal semi-constrained, with an uncemented acetabular component prosthesis – Class III 21 CFR 888.3320 Hip joint metal/ metal semi-constrained, with cemented acetabular component prosthesis – Class III
Device Product Code and Panel Code:	Orthopedics/87/KWA, JDL

DEVICE INFORMATION

A. INTENDED USE

The CONSERVE® PLUS QUADRA-FIX™ Acetabular Shell 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

B. DEVICE DESCRIPTION

The design features of the CONSERVE® PLUS QUADRA-FIX™ Acetabular Shell are summarized below:

- Manufactured from cast cobalt-chromium-molybdenum conforming to ASTM F75
- Porous coated with CoCrMo (ASTM F75) sintered beads with or without HA coating
- Available sizes: 36mm-56mm ID
- 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
- Flange with screw holes on the rim of the shell to enhance fixation
- Cancellous flange screws available in 35-80 mm lengths

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The indications for use of the CONSERVE® PLUS QUADRA-FIX™ Acetabular Shell are identical to the predicate devices. The design features and materials of the CONSERVE® PLUS QUADRA-FIX™ Acetabular Shell are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified device has not changed relative to the predicate devices. The safety and effectiveness of the CONSERVE® PLUS QUADRA-FIX™ Acetabular Shell 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

APR 18 2006

Wright Medical Technology, Inc.
c/o Mr. Matt Paul
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

Re: K060356/S1
Trade/Device Name: CONSERVE® PLUS QUADRAFIX™ Acetabular Shell
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA, JDL
Dated: March 17, 2006
Received: March 20, 2006

Dear Mr. Paul:

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.

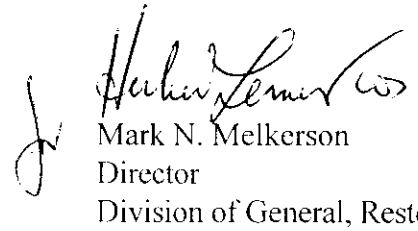
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

K060356

Indications for Use

510(k) Number (if known):

Device Name: CONSERVE® PLUS QUADRAFIX™ Acetabular Shell

Indications For Use:

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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

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)

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

510(k) Number K060356