

K042530

DEC 17 2004

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 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the CONSERVE® Plus HA Acetabular Shell.

Submitted By: Wright Medical Technology, Inc.
Date: September 15, 2004
Contact Person: Jeanine H. Redden
Regulatory Affairs Specialist II
Proprietary Name: CONSERVE® Plus HA Acetabular Shells
Common Name: Acetabular Shells
Classification Name and Reference: 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/KWA

DEVICE INFORMATION

A. INTENDED USE

The CONSERVE® Plus HA Acetabular Shells 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 HA Acetabular Shells are intended for single patient use only.

B. DEVICE DESCRIPTION

A Hydroxylapatite (HA) coating is being added to the following previously cleared CONSERVE® Shells: CONSERVE® Plus Thin Shell, CONSERVE® Plus Spiked Shell, CONSERVE® Total SuperFix Shell, CONSERVE® Plus Thick Shell

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The CONSERVE® Plus HA Acetabular Shells are substantially equivalent to the predicate devices previously cleared for market. The safety and effectiveness of the CONSERVE® Plus HA Acetabular Shells is adequately supported by the substantial equivalent information, materials data, and testing results provided within this Premarket Notification.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jeanine H. Redden
Regulatory Affairs Specialist II
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

DEC 17 2004

Re: K042530

Trade/Device Name: Conserve® Plus HA Acetabular Shells

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

Dated: December 7, 2004

Received: December 8, 2004

Dear Ms. Redden:

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.

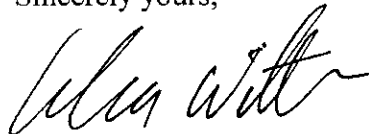
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Ms. Jeanine H. Redden

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 Witten, Ph.D., M.D.

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): K042530

Device Name: CONSERVE® Plus HA Shells

Indications For Use:

The CONSERVE® Plus HA Shells 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:

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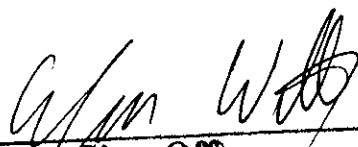
Prescription Use X
(Part 21 CFR 801 Subpart D)

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

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