

OCT 27 1998

Exhibit I

510(k) Summary
SUMMIT™ Acetabular System

K983014

Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

A. Contact Person:

Janet G. Johnson, RAC
Associate Regulatory Affairs Specialist
(508) 828-3466

B. Device Information:

Proprietary Name: SUMMIT™ Acetabular System
Common Name: Acetabular Cup and Liner
Classification Name: Hip joint metal/ polymer semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II, per 21 §CFR 888.3358
Product Code: 87 LPH

C. Indications for Use:

The SUMMIT™ Acetabular System is indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for revision of previous hip arthroplasty and for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

All SUMMIT™ porous -coated acetabular shells are indicated for cementless application.

D. Device Description:

The SUMMIT™ Acetabular System is part of a modular system for use in total hip replacement. The acetabular component is provided as two separate units, an outer shell composed of titanium alloy (Ti-6Al-4V) with a commercially pure titanium porous coating and a liner of ultrahigh molecular weight polyethylene (UHMWPE), which locks into the outer shell. The acetabular component articulates with a femoral head of an appropriate diameter.

The acetabular shell has a porous-coated surface and is provided No-Hole, Cluster Hole, Multi-Hole, Spiked and Deep Profile configurations that accept liners for 22.225, 26, 28 and 32mm femoral head sizes; as well as 0°, 10°, and 15° face angles.

Also available for use with the SUMMIT™ Acetabular System are an apical hole plug and a variety of bone screws, all composed of titanium alloy.

E. Substantial Equivalence:

The SUMMIT™ Acetabular System is substantially equivalent in terms of intended use, materials, design, sterilization method, and packaging to the ZTT™ I and II Acetabular Cup (K951000), Arthopor™ I and II (K955511), PFC™ Acetabular Cup (K931189 and K930712) and the DePuy DURALOC® 300 Series (K951301).

The determination of substantial equivalence for this device was based on a detailed device description, performance testing and conformance with voluntary performance standards, e.g. ASTM F-67, ASTM F136 and ASTM F1044.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Janet G. Johnson, RAC
Associate Regulatory Affairs Specialist
Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K983014
Trade Name: Summit™ Acetabular System
Regulatory Class: II
Product Code: LPH
Dated: August 27, 1998
Received: August 28, 1998

Dear Ms. Johnson:

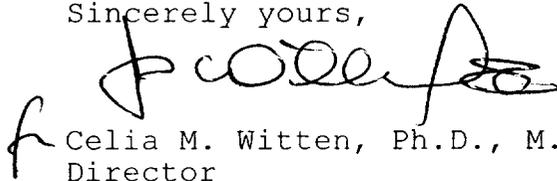
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a large, stylized initial 'C' on the left.

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

Enclosure

510(k) Number (if known)

K983014

Device Name

SUMMIT™ Acetabular System

Indications For Use

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(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes
(Per 21 CFR §801.109)

OR

Over-the-Counter Use No

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number

K983014