K980286

APR 3 1998

Exhibit I

510(k) Summary
ULTIMA® Acetabular Roof Reinforcement Ring

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

1. ***Contact Person:***

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

2. ***Device Information:***

Proprietary Name:	ULTIMA® Acetabular Roof Reinforcement Ring
Common Name:	Acetabular Roof Reinforcement Ring
Classification Name:	Hip joint metal/ polymer semi-constrained cemented prosthesis
Regulatory Class:	Class II, per 21 §CFR 888.3350
Product Code:	87 JDI

3. ***Indications for Use:***

The ULTIMA® Acetabular Roof Reinforcement Ring 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 patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis, and disability due to previous fusion, where bone stock is inadequate for other reconstructive techniques.

The Ultima® Acetabular Roof Reinforcement Ring is secured in the prepared acetabulum using a combination of Polymethylmethacrylate (PMMA) bone cement, bone allograft, and cancellous screws to provide stabilization.

4. ***Device Description:***

The ULTIMA® Acetabular Roof Reinforcement Ring is a support component for the reconstruction of the acetabulum and is composed of commercially pure titanium (cp Ti). The ULTIMA® Acetabular Roof Reinforcement Ring is a hemispherical shell with a mesh of screw holes covering the shell to allow for use with cancellous screws for additional stabilization.

The ULTIMA® Acetabular Roof Reinforcement Ring is used in conjunction with the ULTIMA® UHMWPE Acetabular Cup and Augmented UHMWPE Cup, and is held into the prepared acetabulum using a combination of Polymethylmethacrylate (PMMA) bone cement, bone allograft, and cancellous screws to provide primary stabilization.

The ULTIMA® Acetabular Roof Reinforcement Rings will be available in a range of designated sizes from 40mm through 62mm in 2mm increments. The nominal outer diameter of the ULTIMA® Acetabular Roof Reinforcement Ring is the same as the designated size.

The instrumentation used for implanting the ULTIMA® Acetabular Roof Reinforcement Ring includes a drill guide, 70mm drill, flexible shaft, depth gauge, tap and screw clamp, hemispherical reamers and a universal screw driver.

5. ***Substantial Equivalence:***

The ULTIMA® Acetabular Roof Reinforcement Ring is substantially equivalent in terms of intended use, materials, design, sterilization method, and packaging to the Protek Roof Reinforcement Ring (K953578).

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 1998

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

Re: K980286
Trade Name: ULTIMA® Acetabular Roof Reinforcement Ring
Regulatory Class: II
Product Code: JDI
Dated: January 23, 1998
Received: January 26, 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 (Premarket 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 premarket 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,

for 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) *K980286*

Device Name *ULTIMA® Acetabular Roof Reinforcement Ring*

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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980286

Prescription Use X OR Over-the-Counter Use____
(Per 21 CFR §801.109)

(Optional Format 1-2-96)