SEP 11 1997

Summary of Safety and Effectiveness Data for the ULTIMA® and ULTIMA® LX Cemented Femoral Stem

Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

K972435

Contact Person

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Name of Device

Proprietary Name:	Ultima® and Ultima® LX Cemented Femoral Stem
Common Name:	Hip Prosthesis
Classification Name:	Hip/joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class:	Class II by 21 CFR 888.3350
Product Code:	87 JDI
Owner/Operator No.:	9001269

Device Classification

This device has been placed in Class II for Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR § 888.3350.

Statement of Substantial Equivalence

The modifications to the ULTIMA Cemented Femoral Stem which include surface finishes of polished and grit blast, collared and collarless (ULTIMA LX) and an increase in offset, and a larger proximal slot are substantially equivalent and identical in material and in function to the ULTIMA Total Hip System Cemented Femoral Stem cleared for marketing under premarket notification #K924379 (February 12, 1993).

The subject device is composed of similar materials to the predicate device mentioned above. Further, the intended use, design, and manufacture of the modified ULTIMA and ULTIMA LX Cemented Femoral Stem are substantially equivalent to those currently distributed. Additionally, the packaging and method of sterilization utilized for the ULTIMA and ULTIMA LX Cemented Femoral Stem are the same as those used for the previously mentioned predicate device.

Indications for Use

The ULTIMA and ULTIMA LX Cemented Femoral Hip Stem is indicated for use in total or partial 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, traumatic and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital epiphysis, and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The ULTIMA and ULTIMA LX Cemented Femoral Stem is indicated for use only with PMMA bone cement.

Physical Description

The ULTIMA and ULTIMA LX Cemented stem is a femoral component for use in total or partial hip arthroplasty procedures. It is designed to be implanted with Polymethylmethacrylate bone cement (PMMA) and used in conjunction with a total hip acetabular component and modular hip head. The ULTIMA and ULTIMA LX Femoral Hip Stems can be used in either the right or left hip.

The stem body design is derived from that of the primary ULTIMA stems K#924379. These stems will be offered in both a collared and collarless (ULTIMA LX) design, with either a polished or grit blast finish and a larger proximal slot. The stems have also been designed with a proximal slot to allow the surgeon an additional instrumentation choice during the seating of the implant.

Both the ULTIMA and ULTIMA LX femoral components are available with either a neck angle of a 135° (centralized) or a neck angle of 130° (medialized) to allow for more accurate anatomical head positioning for the patient. The ULTIMA and ULTIMA LX femoral components can be utilized with the P.F.C. Modular Hip Heads (previously cleared K# 893872) of various neck heads diameters (22.225, 26, 28, and 32 mm) and three neck lengths of standard, +5 mm and +10 mm. The 28 mm head and the 32 mm head are also available with a neck length of -3 mm and -5 mm, respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Mary E. Gray
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325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K972435
Ultima® and Ultima® LX Cemented Femoral Stem
Regulatory Class: II
Product Code: JDI
Dated: June 27, 1997
Received: June 30, 1997

Dear Ms. Gray:

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,

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

Indications for Use
for the
ULTIMA® and ULTIMA® LX
Cemented Femoral Stems

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Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972435