

K965198

Summary of Safety & Effectiveness Data for the ULTIMA* TPS Cemented Stem

JUL 23 1997

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

1. Contact Person

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

2. Device Name

Proprietary Name: ULTIMA* TPS Cemented Stem
Common Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Classification Name: Prosthesis, Hip
Regulatory Class: Class II by 21 CFR § 888.3350
Product Code: 87JDI
Owner/ Operator # 9001269

3. Device Classification

Classification for ULTIMA* TPS Cemented Stem has been placed in Class II by 21 CFR § 888.3350

4. Statement of Substantial Equivalence

The safety and effectiveness of the ULTIMA* TPS Cemented Stem is substantially equivalent in terms of function to the Howmedica Exeter hip stem (#K891454) and to the Zimmer CPT hip stem. Furthermore, testing results demonstrate that the ULTIMA* TPS Cemented Stem is substantially equivalent by withstanding a maximum load of 2,300N force, 5,000,000 cycles, and, as such meets the set criteria for the establishment of "substantial equivalence".

5. Indications for Use

The ULTIMA* TPS Cemented Stem is indicated for use in total or partial hip replacement procedures for patients suffering severe pain and disability due to:

1. structural damage in the hip joint from rheumatoid arthritis,
2. osteoarthritis,
3. post-traumatic arthritis,
4. collagen disorders,
5. avascular necrosis,
6. nonunion of femoral fractures,
7. congenital hip dysplasia,
8. protrusio acetabuli,
9. slipped capital femoral epiphysis, and
10. disability due to previous fusion where bone stock is inadequate for other reconstruction techniques.

The ULTIMA* TPS Cemented stem is indicated for use only with PMMA bone cement.

6. Physical Description

The ULTIMA* TPS Cemented Stem is forged from a Cobalt-Chromium alloy which conforms to ASTM F799 (EXHIBIT IV); this material has high strength and good hardness properties and is also highly immune to fatigue. The ULTIMA* TPS Cemented Stem is polished to a bright finish on all surfaces below the spigot and can be used interchangeably in either the left or the right hip. The stem is straight, tapering towards the distal tip in both the mediolateral and anteriorposterior sections. It does not have a proximal collar.

The ULTIMA* TPS Cemented Stem has a 10/12 Morse taper; it will be available in six sizes (0, 1 - 5), each of the 1 - 5 sizes have a choice of either a 37.5 mm (standard) offset, or a 44.0 mm (medialized "M") offset. In addition to this central range, there shall be two long stem options. The stem can be used with various neck heads (22.225, 26, 28 and 32 mm) as well as neck options (-5 (32), -3 (28), 0, +5 and +10). All of the stems in the range have a neck angle of 125°.

Stem Size	Trunnion Designs	Offset	Neck Heads	Neck Options	Neck Angle
0,1,2,3,4,5	10/12 taper	37.5 / 44.0mm	22.225, 26, 28, 32 mm	-5 (32), -3 (28), 0, +5, +10	125°

Distal Centralizer The distal centralizer that is used with the ULTIMA* TPS stem comes in a range of sizes and is manufactured from PMMA. There are three wings on the centralizer which ensure the orientation of the stem distally. These increase in size through the centralizer range to deal with the variation in anatomy of the medullary canal. In revision surgery, a "wingless" centralizer is required, thus a 7mm diameter version is available which simply acts to provide the void, and does not centralize the stem.

Table 1. Similarities and Differences Matrix

	ULTIMA* TPS Cemented Stem	Howmedica Exeter hip stem	Zimmer CPT hip stem
DESIGN			
Polished	Yes	Yes	Yes
Collarless	Yes	Yes	Yes
Double-taper geometry	Yes	Yes	Yes
INTENDED USE			
Total / partial hip replacement	Yes	Yes	Yes
Used with distal centralizer	Yes	Yes	Yes
MATERIALS			
Orthinox™ (stainless steel alloy)	No	Yes	No
Zimtron™ (stainless steel alloy)	No	No	Yes
Cobalt-Chromium- Molybdenum	Yes	No	No



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 23 1997

Re: K965198
Ultima* TPS Cemented Stem
Regulatory Class: II
Product Codes: JDI and KWL
Dated: April 22, 1997
Received: April 25, 1997

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.

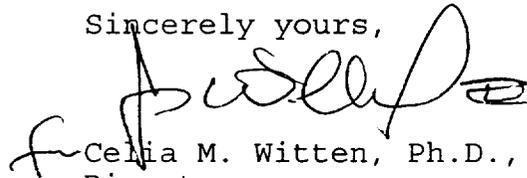
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Janet G. Johnson

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* TPS Cemented Stem**

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

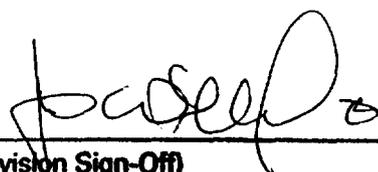
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Prescription Use _____
(Per 21 CFR 801.109)



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

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