

K982812

DEC 4 1998

**Summary of Safety and Effectiveness Data for the
G2 Total Hip System Femoral Stem (11/13 Taper)**

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

Contact Person _____

Mary E. Gray
Associate Regulatory Affairs Specialist
Phone: (508) 828-3545
Fax: (508) 828-3212

Name of Device _____

G2 Total Hip System Femoral Stem (11/13 Taper)

Device Classification _____

This device has been placed in Class II for Hip joint femoral (hemi-hip) metal /polymer cemented or uncemented prosthesis per 21 CFR § 888.3390.

Physical Description _____

G2 Cementless Femoral Stem

The cementless G2 femoral stems are made of the titanium alloy which is microtextured/roughened and available in 12 sizes with both a standard neck length and an offset neck length. These stems are designed with a series of anterior and posterior fins on the proximal portion of the press fit stem and a proximal to distal taper. The design features of the press fit stem allow for axial load transfer to the bone while minimizing shear loads at the stem and bone interface. The design also features initial torsional stability, enhancement of load transfer and the minimizing of micromotion.

G2 Cemented Femoral Stem

The cemented G2 stems are forged cobalt chromium with a polished surface and are available in 6 sizes, with both standard and offset neck lengths. They have a double taper collarless geometry with a proximal lateral flange, as well as mid shaft PMMA cement spacers to allow for centralization of the stem in the cement. The design features of the polished stem allow for proper seating of stem in cement, reduction of torsional stresses in the proximal section of the cement mantle, and potentially minimize cement debris at the stem interface during micromotion.

Indications for Use

The G2 Total Hip System Femoral Stems (11/13 Taper) are 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 this prosthesis is also indicated for patients with congenial hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis, and disability due to previous fusion, where bone stock is inadequate for other reconstructive techniques.

The G2 Polished Femoral Stem (11/13 taper) is indicated for use only with PMMA bone cement.

The G2 Microtextured Femoral Stem (11/13 taper) is not indicated for use with PMMA bone cement.

Summary of Testing

The G2 Total Hip System Femoral Stems (11/13 taper) were evaluated following the ISO standard titled 7206-4- Implants for Surgery - Partial and Total Joint Prosthesis - Part 4 which ensures conformance to the FDA's Draft Guidance Document for Femoral Stem Prosthesis. Test results for both the titanium and cobalt chrome femoral stems were provided in this submission and demonstrated conformity to the standard.

Statement of Substantial Equivalence

The G2 Total Hip System Femoral Stems are substantially equivalent in material and function to the following list of commercially distributed products:

Zimmer Versys™ Enhanced Taper Hip System	K964769
Zimmer Heritage™ Hip System	K963109
Wright Resolution™ Microtextured Femoral Component	K933570
Howmedica Precision Osteolock™ Hip System	K944592
Johnson & Johnson Professional, Inc. P.F.C.® 2 Hip System	K945518
Johnson & Johnson Professional, Inc. ULTIMA® Fx Femoral Hip System	K963885
Johnson & Johnson Professional, Inc. ULTIMA® LX Femoral Hip System	K972435 K924379



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 4 1998

Ms. Mary E. Gray
Associate Regulatory Affairs Specialist
Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K982812
Trade Name: G2 Total Hip System Femoral
Stems (11/13 Taper)
Regulatory Class: II
Product Codes: LZ0, JDI, and KWY
Dated: September 30, 1998
Received: October 1, 1998

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.

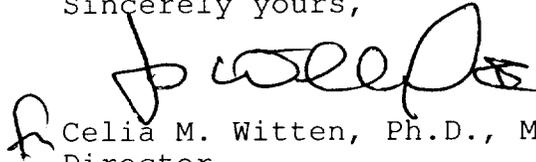
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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". The signature is written in a cursive style with a large initial "C" and "W".

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)
Device Name

K982812

G2 Total Hip System
Femoral Stem (11/13 Taper)

Indications For Use

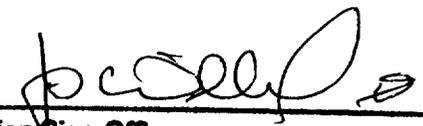
The G2 Total Hip System Femoral Stems (11/13 Taper) are indicated for use in total or partial hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, traumatic and non-union of femoral fractures. Use of this prosthesis is also indicated for patients with congenial hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis, and disability due to previous fusion, where bone stock is inadequate for other reconstructive techniques.

The G2 Polished Femoral Stem (11/13 taper) is indicated for use only with PMMA bone cement.

The G2 Microtextured Femoral Stem (11/13 taper) is not indicated for use with PMMA bone cement.

(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 K982812

Prescription Use X
(Per 21 CFR §801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)