# 510(k) Summary
# UNI-ROM™ Femoral Hip Stem

FEB - 6 1998
K974351

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:** | UNI-ROM™ Total Hip System Femoral Stem |
| **Common Name:** | Femoral Stem Prostheses |
| **Classification Name:** | Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis |
| **Regulatory Class:** | Class II, per 21 §CFR 888.3358 |
| **Product Code:** | 87 LPH |

3. **Substantial Equivalence:**

The UNI-ROM™ Femoral Hip Stem is substantially equivalent in terms of intended use, materials, design, manufacturing processes, sterilization method, packaging and performance to the S-ROM Femoral Hip Stem (K961939, K954935 and K851422) and P.F.C. 2 Femoral Stem (K945518 and K935452).

4. **Indications for Use:**

The UNI-ROM™ Total Hip Stem 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.

5. **Physical Description:**

The UNI-ROM™ Femoral Hip Stem is a one-piece porous coated hip stem that manufactured from titanium alloy (Ti-6Al-4V). The stem is designed with steps on the outer surface of the porous-coated area to encourage compressive loading of the bone there by allowing for uncemented fixation. The proximal circumferential area is porous coated with commercially pure titanium. The UNI-ROM™ Femoral Hip Stem is anatomically shaped with flutes and a coronal slot in the distal portion of the stem.

The UNI-ROM™ Femoral hip stem can be used in either the right or left hip and mates with the femoral hip head using an 11/13 Morse-type taper. Further, the femoral stem is designed to accept an S-ROM Co-Cr Femoral head or an S-ROM Ceramic Femoral Head.

The determination of substantial equivalence for this device was based in part on bench top performance data.

**Similarities and Differences Matrix**

| | UNI-ROM™ Femoral Hip Stem | S-ROM® Femoral Hip Stem (K961939, K954935 and K851422) | P.F.C. 2 Femoral Stem - Size Small (K945518 and K935452) |
|---|---|---|---|
| DESIGN | | | |
| Femoral Head locks onto the stem with a Morse-type taper lock | Yes | Yes | Yes |
| Intended for non-cemented fixation | Yes | Yes | Yes |
| Distal Slot | Yes | Yes | No |
| Distal Flutes | Yes | Yes | Yes |
| Adjunct to a Total Hip System | Yes | Yes | Yes |
| Anatomically Shaped | Yes | Yes | Yes |
| Press Fit | Yes | Yes | Yes |
| Porous Coating | Proximal | Proximal Sleeve | Proximal |
| Recommended for use with: | Femoral Heads with a 11/13 Morse Type Taper | Femoral Heads with a 11/13 Morse Type Taper | Femoral Heads with a 10/12 Morse Type Taper |
| INTENDED USE | | | |
| Indicated for use in primary hip replacement procedures. | Yes | Yes | Yes |
| MATERIALS | | | |
| Ti-6Al-4V Substrate | Yes | Yes | Yes |
| Commercially Pure Titanium Porous Coating | Yes | Yes | No |
| Ti-6Al-4V Porous Coating | No | No | Yes |

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 and Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

FEB - 6 1998

Re: K974331
Trade Name: UNI-ROM™ Femoral Hip Stem
Regulatory Class: II
Product Code: LPH
Dated: November 17, 1997
Received: November 18, 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.

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)** K974331

**Device Name** **UNI-ROM™ Femoral Hip Stem**

**Indications For Use:**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974331

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

(Optional Format 1-2-96)