

AUG 29 1986

EXHIBIT III

K962248

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

P.F.C. Ceramic Hip Head indicated for use with the P.F.C. Cemented Hip Stem,
Ultima Cemented Hip Stem and Ultima Cemented Long Stem

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

1. Contact Person

Anne M. Griffin, Regulatory Affairs Specialist, (508) 828 - 3107.

2. Name of Device

P.F.C. Ceramic Hip Head indicated for use with the P.F.C. Cemented Hip Stem, Ultima Cemented Hip Stem and Ultima Cemented Long Stem. The P.F.C. Ceramic Hip Head has been cleared under 510(k) K933275.

3. Device Classification

Ceramic Hip Heads have been placed into Class II by 21 CFR 888.3353.

4. Statement of Substantial Equivalence

The Ceramic Hip Heads and the Cemented Hip Stems are identical in design, materials and indications for use to those already cleared for domestic commercial distribution. This Premarket Notification is for the labeling of the Hip Stems for use with the Ceramic Hip Head. The mating of the Co-Cr-Mo alloy trunnion of the Hip Stems does not alter the safety and effectiveness of the devices. The test results obtained for the Ceramic Hip Head exceed the requirements of the Guidance Document ("Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems"- Draft, January 10, 1995).

5. Indications for Use

The Hip Stem components 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 and non-union of femoral fractures. These devices are indicated for use only with Bone Cement (PMMA).

The P.F.C. Ceramic Hip Head is designed as a modular head, compatible with Johnson & Johnson Professional, Inc.'s femoral stems with a 12/14 Morse-type taper.

6. Physical Description

All Hip Stem components are manufactured using cobalt-chromium-molybdenum alloy that complies with ASTM F799. The Ceramic Hip Head is manufactured of Yttrium Stabilized Zirconium Oxide (Zirconia), also known as PROZYR®.

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