

K961939

AUG 13 1996

Appendix I

510(k) Summary of Safety and Effectiveness

S-ROM® Total Hip System

S-ROM® Femoral Hip Stem - Sizes 12 x 06 x 115 and 12 x 07 x 115

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Name of Device

Proprietary Name: S-ROM® Femoral Hip Stem - Sizes 12 x 06 x 115 and 12 x 07 x 115
Common Name: Femoral Hip Stem
Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Device Classification

This device has been placed in Class II for Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR §888.3358.

Statement of Substantial Equivalence

The S-ROM Femoral Hip Stems (Sizes 12 x 06 x 115 and 12 x 07 x 115) are substantially equivalent to several hip prostheses currently marketed in the United States for hip replacement including the S-ROM Femoral Hip Stems cleared under #K851422, #K913231, #K921111, #K934412, #K910664 and #K954935. The subject device is also substantially equivalent to hip prostheses such as the P.F.C.® Total Hip System (#K944518).

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The subject device is composed of the same materials as similar stems marketed in the United States. Further, the intended use, design, and manufacture of the S-ROM femoral hip stems 12 x 06 x 115 and 12 x 07 x 115 are substantially equivalent to currently distributed hip stems. Additionally, the packaging and method of sterilization are currently utilized for other S-ROM stems, as well as other stems currently distributed in the United States.

Indications for Use

The S-ROM Femoral Hip Stem - Sizes 12 x 06 x 115 and 12 x 07 x 115 is intended for non-cemented fixation as the femoral component of a total hip replacement system. The stems are indicated for use in primary and revision replacement surgery. The prosthesis may be used for the following conditions, as appropriate:

- Osteoarthritis;
- Traumatic Fractures;
- Rheumatoid Arthritis;
- Avascular Necrosis; and
- Congenital Dislocation.

Physical Description

The S-ROM Femoral Hip Stems (Sizes 12 x 06 x 115 and 12 x 07 x 115) are manufactured from Ti-6Al-4V, the same material used to manufacture the S-ROM femoral hip stems in the larger sizes and that has been used in orthopaedic implants for many years with established clinical success. The S-ROM Femoral Hip Stems are anatomically shaped with flutes and a coronal slot in the distal portion of the stem. The size 12 x 06 x 115 and 12 x 07 x 115 stems, as well as the larger size S-ROM femoral hip stems, can be used in either the right or left hip.

Testing was conducted per the FDA's *Draft Guidance Document for Femoral Stem Prostheses*, in accordance with ISO 7206-4.

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