K954800

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Interim Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21CFR 807, this is to serve as a Summary of Safety and Effectiveness for the APR® Hip System with Calcitite®-Coated Cancellous-Structured Titanium (CSTi).

Submitter:	Intermedics Orthopedics®, Inc. 9900 Spectrum Drive Austin, Texas 78752 (512) 432-9900
Date:	February 5, 1996
Contact Person:	Jacquelyn Hughes Manager, Regulatory Affairs
Classification Name:	Hip Joint Metal/Polymer/Metal Semi-Constrained Porous Coated Uncemented Prosthesis (CFR 888.3358)
Common/Usual Name:	Biologically fixed total hip prosthesis, semi-constrained
Trade/Proprietary:	APR® Hip System with Calcitite®-Coated Cancellous-Structured Titanium (CSTi)

PRODUCT DESCRIPTION/SUBSTANTIAL EQUIVALENCE:

The APR Total Hip System consists of four basic components: anatomically shaped APR II and APR II-T femoral stems, Cobalt Chrome (CoCr) and ceramic femoral heads, APR acetabular metal shells, and Ultra-High Molecular Weight Polyethylene (UHMWPe) acetabular inserts. The porous surfaces of the femoral and acetabular components are coated with Calcitite® coating.

Femoral Components

The APR II and APR II-T femoral components are anatomically designed with right and left components available in six regular sizes and six large sizes. The components are manufactured from wrought Ti-6Al-4V (ASTM F136). The APR II and APR II-T anatomic femoral prostheses are fabricated with a neck and stem designed to match the natural shape and curve of the femur. Calcitite® coating has been applied to the Cancellous Structured Titanium (CSTi) located on the inferior side of the collar as well as the anterior, posterior and medial surfaces of the proximal femoral body. Additionally, the coating is also applied to the CSTi found on the lateral surface of the APR II-T stem. A morse-type taper on the proximal aspect of the stem permits attachment of one of a variety of femoral heads.

Femoral Head Components

The CoCr metallic and Zirconia and Alumina ceramic modular femoral heads attach to the APR II and APR II-T femoral components via a Morse-type taper. The CoCr femoral heads are manufactured from wrought CoCr conforming to ASTM F799. The ceramic heads are manufactured from either zirconium oxide (zirconia) or aluminum oxide (alumina). The CoCr femoral heads are available with the IOI taper (26mm, 28mm and 32mm diameters) or 12/14 taper (22mm, 26mm, 28mm and 32mm diameters); the ceramic heads are available in 28mm and 32mm

diameters and fit on the 12/14 taper. A variety of neck lengths are offered for each head type.

Acetabular Component

The APR acetabular shell is a hemispherical modular component manufactured from wrought Ti-6Al-4V (ASTM F136) conforming to ASTM F136. The shell is fixed into place using bone screws. Calcitite-coated CSTi has been applied to the outer spherical surface of the component, with the exception of the dome and region adjacent to the screw holes. The modular design of the acetabular shell permits use of a variety of acetabular inserts. The shell is available in 16 sizes.

Acetabular Inserts

The APR acetabular inserts are manufactured from UHMWPe (ASTM F648) and are available in three types: standard, hooded and hooded protrusio. They are available in various sizes and diameters to articulate with the femoral heads. The plastic inserts are snapped into the metal shell at the time of surgery and can be fixed at one of 12 positions. Antirotation is achieved with a pin on the plastic insert that fits into a slot on the acetabular shell.

The APR Hip System with Calcitite-Coated CSTi is indicated for noncemented use in skeletally mature individuals undergoing primary surgery for rehabilitating hips damaged as a result of Inflammatory Joint Disease (e.g., rheumatoid arthritis) or Noninflammatory Degenerative Joint Disease (e.g., osteoarthritis, avascular necrosis, traumatic arthritis, fracture dislocation of the hip and femoral neck fracture).

Fatigue analysis and stem strain gauge analysis indicated that both the APR and APR II-T femoral stems should survive physiologic loading. Axial push-out, torque-out, and lever-out testing performed on the APR acetabular insert and shell indicated that the device should perform favorably in-vivo.

Fatigue, tensile and shear test of the bond between the Calcitite-porous surface coating and the substrate indicate that the coating bond strength should be adequate for the intended use of the device. Additionally, *in vivo* studies showed that the interface between the bone and porous coating exhibited strength over time.

A clinical study conducted under an approved IDE showed that good to excellent clinical results can be expected in noncemented use of this prosthesis provided that stable initial fixation can be achieved.

The APR® Hip System with Calcitite®-Coated Cancellous-Structured Titanium (CSTi) is similar to the Intermedics Orthopedics APR II and APR II-T with CSTi, the Intermedics Orthopedics APR and APR II with Calcitite Coating, the Howmedica Precision Osteolock, and the Osteonics Omnifit with HA.

148