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K961890

Summary of Safety and Effectiveness

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Trade Name: Foundation™ Non-Porous Stem

Common Name: Cemented total hip

Classification Name: Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3350

Description: The proximal body of the Foundation™ Non-Porous Stem is trapezoidal in cross-sectional geometry and tapers proximal to distal and lateral to medial. The proximal body has two ribs on the anterior and posterior surfaces that run the length of the proximal body. Polymethylmethacrylate "buttons" are placed on the anterior, posterior, lateral and medial surfaces of the proximal body to assure that the implant is centered in the metaphyseal region of the femur with a 1.5 mm cement mantle. The proximal body of the femoral stem is grit blasted to a surface of 4-6 μ . This device is fabricated from forged CoCrMo alloy.

The distal portion of the stem is conical in shape. It necks down at the distal end to receive a flanged PMMA canal centralizer. This centralizer assures that the distal stem is centered in the femoral canal and helps to maintain an even cement mantle around the distal stem. The Foundation 9 mm Forged Cemented Stem has a calcar collar and has a Morse type taper to receive modular heads. The neck/stem angle is 132°.

Intended Use: The Foundation 9 mm Forged Cemented Stem is intended for treatment of patients who are candidates for total or hemi-hip arthroplasty. The indications for use of the total hip replacement prosthesis include: noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments where devices have failed; and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is unmanageable using other techniques. It is intended to be used with cement with acetabular components or with unipolar heads.

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510(k) Submission
Foundation™ 9mm Forged Cemented Stem

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the Foundation® Forged Cemented Stems approved for commercial distribution in K952191, CoCrMo substrate, distal femoral canal centralizer, proximal cement spacers, calcar collar, proximal ribs on body, roughened proximal body, modular heads and unipolar heads.

Test Results: This stem survived a fatigue load of 3300 N.

Laboratory testing of the Morse type taper was conducted.