

SEP 19 1996

Summary of Safety and Effectiveness

K962560

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Trade Name: Vitality Hip Stem

Common Name: Cemented total hip

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

Description: The Vitality Hip Stem is rectangular in cross-sectional geometry and tapers proximal to distal and lateral to medial. The proximal half of the body of the femoral stem is grit blasted to a surface of 4-6 μm . This device is fabricated from forged CoCrMo alloy.

The Foundation Vitality Hip Stem is available with and without a calcar collar and has a Morse type taper to receive modular heads. The neck/stem angle is 130° for sizes 1-2 and 132° for sizes 3-6.

Indications for Use: The Vitality Hip 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, bipolar and CoCrMo femoral heads.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the Foundation® Forged Cemented Stems (K952191), Foundation® 9 mm Forged Stems (K961890), CoCrMo substrate, calcar collar, roughened proximal body, modular heads, bipolar and unipolar heads. The design is comparable to the predicate device the Lima Universal Stem (K885146, K910836).

Test Results: Laboratory testing of the Morse type taper was conducted. Theoretical testing of the maximum stresses was compared to the Foundation® 9 mm Forged Stem.