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510(k) Summary
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Contact Person:
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Name of Device

Classification Name: Hip Joint Femoral Metal/Polymer Semi-Constrained Prosthesis Class II per 21 CFR § 888.3390. This falls under the Orthopaedics panel/87.

Common Name: Hip Prosthesis.

Trade Name/Proprietary Name: ULTIMA® Fx Femoral Hip Stems

Performance Standards: No performance standards have been developed for this device.

Predicate Devices

Biomet Hip Fracture System
Biomet Bi-Metric Hip System -- Collarless
Biomet APF Series Modular APF (Anatomical Press Fit)
Zimmer VerSys™ Hip System
Wright McCutchen Hip Stem
Wright Nexus™ Hip Stem
Wright Resolution™ Microtextured Femoral Stem
Howmedica PercisionOsteolock™ Hip System
Osteonics Omnifit® Normalized Stem -- Collarless

Description of Device

The ULTIMA Fx Femoral Hip Stems will be offered in both a cemented design and uncemented design, both manufactured of cobalt-chromium-molybdenum alloy (Co-Cr-Mo). The stems will be offered with the following features:

Feature	ULTIMA Fx Cemented Stem	ULTIMA Fx Press-Fit Stem
Distal Diameter	8 - 11 mm	10.5 - 15 mm
Length	130 - 165mm	125 - 165 mm
Cement Mantle	2.0 - 3.6 mm	N/A
Offset	37 - 46 mm	34 - 46 mm
Cobra Flange	Yes	No

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The ULTIMA Fx Femoral Hip Stems can be used in either the right or left hip, and are designed to mate with the following hip heads.

P.F.C.® Hip Heads (10/12 Taper)
ULTIMA® Unipolar Hip Heads (10/12 Taper)

Intended Use

The ULTIMA Fx Femoral Hip Stem is 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, traumatic and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis, and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

Technological Characteristics Compared to Predicate Device

The ULTIMA Fx Femoral Hip Stems are technically equivalent to the predicate devices mentioned above.