



WRIGHT

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510(k) SUMMARY

Trade/Proprietary Name: PERFECTA® Revision Hip System
Common Name: Wire Spray Coated Femoral Hip Stem
Classification: Class II
Predicate Device: PERFECTA® Hip System by Orthomet, a division of
Wright Medical Technology, Inc. and the Osteonics® Arc
Depositioned Femoral Components

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Description/Intended Use

The PERFECTA® Revision Hip System is a monolithic design femoral component. The device is manufactured from titanium alloy (ASTM F-136) with a titanium alloy wire arc spray coating. The stem is available in two configurations: straight and bowed. All configurations have a calcar platform, from 2.0cm to 3.75cm. All sizes, except for 12mm x 190mm, have a coronal slot. The stem is designed to be press-fit or can be used with bone cement.

The PERFECTA® Revision Hip System is intended to be used in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Substantial Equivalence

The PERFECTA® Revision Hip System is substantially equivalent to the PERFECTA® Hip System by Orthomet, a division of Wright Medical Technology, Inc. and the Osteonics® Arc Depositioned Femoral Components

Testing

The PERFECTA® Revision Hip System demonstrates acceptable fatigue strength. In addition the titanium wire arc spray coating demonstrates less weight loss as compared to the sintered bead control specimen through a comparable range of loads.

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