



SEP 10 1996

Contact Person: Cristie Manuel
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510(k) Summary

Trade/Proprietary Name: PERFECTA® PS Revision Hip Stem
510(k) Number: K962267
Common Name: Plasma Spray Coated Femoral Hip Stem
Classification: Class II
Predicate Devices: PERFECTA® Hip System and PERFECTA® Revision Hip System manufactured by Wright Medical Technology, Inc. and Integral Total Hip System manufactured by Biomet

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 plasma 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 the 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® PS Revision Hip Stem is substantially equivalent to the PERFECTA® Hip System and the PERFECTA® Revision Hip System manufactured by Wright Medical Technology, Inc. and the Integral Total Hip System manufactured by Biomet.

Testing

- Submitted abrasion testing demonstrates that the plasma spray porous coating is comparable to sintered bead coating.
- Submitted fatigue testing demonstrates that the PERFECTA® PS Revision Hip Stem was able to withstand test loading designed to simulate *in vivo* loading.