



WRIGHT

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510(k) Summary

Trade/Proprietary Name: PERFECTA® Plasma Spray Hip System
Common Name: Plasma Spray Coated Femoral Hip Stem
Classification: Class II
Predicate Devices: PERFECTA® Plasma Spray Hip System and PERFECTA® Revision Hip System manufactured by Wright Medical Technology, Inc.

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® Plasma Spray Hip System is manufactured from titanium alloy (ASTM F-136) with a titanium plasma spray coating. The stem is available in standard and reduced flare configurations, collared and collarless. The stem is designed to be press-fit or can be used with bone cement.

The PERFECTA® Plasma Spray Hip System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- 1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- 2) inflammatory degenerative joint disease such as rheumatoid arthritis;
- 3) correction of functional deformity;
- 4) revision procedures where other treatments or devices have failed; and,
- 5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Testing

Submitted abrasion testing demonstrates that the plasma spray porous coating is comparable to sintered bead coating.

Submitted validated finite element analysis indicates that the fatigue strength of the worst case subject device, the PERFECTA® 12mm reduced flare, collarless hip stem, is comparable to the fatigue strength of the predicate PERFECTA® 12mm calcar revision hip stem.

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