K970346

Premarket Notification
510(k) Summary

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In accordance with the Food and Drug Administration Interim Rule to implement provisions of the Safe Medical Devices Act (SMDA) of 1990 and in conformance with 21 CFR 807, this is to serve as a 510(k) Summary for the Kairos™ Orthopaedics Patient Specific Implant (PSI) Hip Femoral Component with HA Coating.

Submitter:
Kairos™ Orthopaedics
819 Striker Avenue, Suite 10
Sacramento, California 95834
Telephone: (916) 646-5403
Fax: (916) 646-5432

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Contact Person:
Brian Cleary
Director, Regulatory Affairs

Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353)

Common Name: Patient Matched Hip Stem

Trade/Proprietary Name: Patient Specific Implant (PSI) Hip Femoral Component with HA Coating

Product Code: 87 LZO

Device Description:
The Kairos™ Orthopaedics Patient Specific Implant (PSI) Hip Femoral Component with HA Coating is designed using the patient's natural bone geometry to construct an implant to better fit and fill the patient's femoral canal relative to other commercially available standard hip stems. Since each stem is matched to a particular patient, a precise device description cannot be provided, as the device design will vary from patient to patient depending upon their unique, naturally occurring bone geometry. Kairos™ Orthopaedics specifies eight design parameters that define an "envelope" of dimensional limits within which all PSI stems are defined.

The PSI Hip Femoral Component with HA Coating is indicated for uncemented use as the femoral component in total hip arthroplasty (THA) for replacing the hip joint of patients whose hip joint has been damaged by degenerative joint disease, fracture or the failure of previous arthroplasty. Each PSI stem is specifically designed for clinical cases where the patient would see added benefit from a femoral component designed to match the natural bone geometry of the femur.

Substantial Equivalence:
Several commercially available standard line hip products are substantially equivalent to the Kairos™ Orthopaedics' PSI Hip Femoral Component with HA Coating with respect to overall design, materials, intended use, and sterilization methods. Additionally, the manufacturing methods and applied surface treatments are substantially the same as those used in the production of a wide range of currently marketed standard line hip products.

It is our understanding that other anatomically based hip stems have received 510(k) clearance in the past, including the following:

1. **Patient Matched Implant (PMI) Hip Femoral Component**
   Biomet, Inc. (Warsaw, Indiana)

2. **Techmedica Continuum Hip System**
   Techmedica, Inc. (Camarillo, California)

3. **Biopro DRG Option Hip Replacement System – Femoral Stem**
   Biopro, Inc. (Port Huron, Michigan)

Of these, Biomet's Patient Matched Implant (PMI) is the most similar and is still presently marketed. Biomet's PMI hip stem is also a patient matched hip stem which uses patient data to design and manufacture a hip stem to match a particular patient's naturally occurring bone geometry. Due to the similarities in the general device design concept, Kairos™ Orthopaedics believes that the Biomet PMI stem is ideal for comparison to demonstrate the substantial equivalence of Kairos™ Orthopaedics' PSI Hip Femoral Component with HA Coating. The table on the following page summarizes these feature comparisons.

Additionally, an engineering stress analysis was performed on the envelope of design parameters to ensure fatigue performance of the PSI Hip Femoral Component with HA Coating comparable to a clinically proven standard hip stem. Mechanical testing performed by Kairos™Orthopaedics on a representative PSI stem verified these stress analysis calculations.

Feature comparisons between the Kairos™ Orthopaedics PSI Hip Femoral Component with HA Coating and Biomet, Inc. PMI hip femoral component. Differences are indicated in **bold** print.

Characteristics	**Subject Device** *Kairos™ Orthopaedics* *Patient Specific Implant (PSI)* ***with HA Coating***	**Predicate Device** *Biomet, Inc.* *Patient Matched Implant (PMI)*
Manufacturer	Kairos™ Orthopaedics	Biomet, Inc.
510(k) Approved	-	Yes
Materials	Wrought or Forged Titanium (Ti-6Al-4V)	**Wrought Cobalt Chromium** (Co-Cr-Mo) or Wrought Titanium (Ti-6Al-4V)
Intended Use	Uncemented	**Cemented/Uncemented**
Patient Matched	Yes	Yes
Collar	Yes	Yes
Distal Flutes	Yes	Yes
Surface Treatments	• Hydroxylapetite (HA) Coating	• Smooth • Grit Blasted • **Plasma Sprayed Coating** • **Ion Nitride (NTS)**
Stem Length from Resection Level	90mm - 300mm	unknown
Distal Diameter	8mm - 20mm	unknown
Patient Information	CT or X-Ray	CT or X-Ray
Sterilization Status	Sterile **& Non-sterile**	Sterile