K961685

510(k) Summary
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Name of Device

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis has been placed in Class II by the FDA under 21 CFR 888.3560. This falls under the Orthopaedics panel/87.

Common Name: Semi-constrained total knee prosthesis.

Trade Name/Proprietary Name: **P.F.C.® Σ Cruciate Retaining Knee System (Size 1.5)**

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

Predicate Device

P.F.C.® Σ Cruciate Retaining Knee System

Description of Device

The P.F.C.® Σ Cruciate Retaining Knee System (Size 1.5) consists of:

1. Size 1.5 asymmetrical Femoral component, both porous & non-porous coated;
2. Size 1.5 Tibial inserts;
3. Size 1.5 All-Polyethylene Tibiae (APT);
4. Size 1.5 Tibial trays;
5. Size 32mm Oval dome patellae, three and single peg.

The device is a prosthetic device intended to replace the natural knee joint. The device is constructed of UHMWPE, Titanium and Co-Cr-Mo alloy.

Intended Use

The P.F.C.® Σ Cruciate Retaining Knee System is indicated for use only with bone cement (PMMA) for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders or pseudogout. This damage may also be the result of trauma or failed prior surgical intervention.

Technological Characteristics Compared to Predicate Device

All technical characteristics are identical to the Predicate Device. The P.F.C.® Σ Cruciate Retaining Knee System (Size 1.5) is identical to the Predicate device except we are introducing smaller sized components.

Performance Tests

The following tests were conducted for a determination of substantial equivalence:

Constraint Testing

Contact Areas between all Interfacing Components

Surface Characteristics of Articulating Surfaces
Modified Surface Data Form Testing
Tibial Insert/Tibial Tray Interlock Testing
Lateral Stability of Patellofemoral Joint
Fixation Testing of Patella Component (Tensile & Shear)
Fatigue Strength of the Tibial Component