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510(k) Summary
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Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

Contact Person:
John Ferros
Phone: 508.880.8287

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 Sigma Knee System (Stabilized Plus)**
Performance Standards: No performance standards have been developed for this device.

Predicate Device

P.F.C.® Σ Sigma Knee System

Description of Device

The Stabilized Plus tibial insert components are used with the existing components of the P.F.C.® Σ Sigma Knee System. The Stabilized Plus tibial insert components have a symmetrical design which can be used for either the left or right knee. The Stabilized Plus tibial insert components have an anterior and posterior snap feature and a reinforcing pin to ensure adequate interlock to the tibial tray. The tibial insert attachment mechanism is identical to the existing TC3 tibial inserts. The Stabilized Plus tibial insert and femoral condylar geometry allow for mixing and matching of sizes: up one size, size to size, and down one size. The device is constructed of UHMWPE, and Titanium.

Intended Use

The P.F.C.® Σ Sigma 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 Sigma Knee System (Stabilized Plus) is identical to the Predicate device except we are introducing the Stabilized Plus tibial insert components.