

JUL - 5 1996

510(k) SUMMARY

K961482

Device: Duracon® Inset Patella with Central Peg

Common Name: Concentric Dome Patella

Classification Name and Reference:

Knee Joint Patellofemorotibial Polymer/Metal/Polymer
Semi-Constrained Cemented Prosthesis
21 CFR 888.3560

Proposed Regulatory Class: Class II

Device Product Code: JWH (OR)

This device, an all-polyethylene concentric dome patella, is intended to be used with the femoral and tibial components of the Duracon® and P.C.A.® MTK II components as a total knee system. This component is intended to be used in the primary and/or revision replacement of the articular surface of the patella.

This patella component is similar in intended use, material, design and operational principles to other legally marketed devices. These devices include: 1) Duracon® Recessed Patella (Howmedica); 2) Duracon® All-Poly Patella (Howmedica); 3) Genesis Biconvex Patella (Smith & Nephew Richards); 4) Omnifit All-Polyethylene Patella (Osteonics); 5) Miller-Galante II All-Polyethylene Patella (Zimmer) and 6) Kinematic® II All-Polyethylene Patella (Howmedica).

All of the devices are fabricated from Ultra-High Molecular Weight Polyethylene which conforms to ASTM Specification F 648. All of the named components have the same intended use. All of the named devices are implanted using bone cement.

Patello-femoral contact area and shear testing were presented, with a comparison to a legally marketed device.

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