

K96/483
510(k) SUMMARY

JUL 9 1996

Device: Duracon® All Polyethylene Patella II

Common Name: All Polyethylene 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 patella, is intended to be used with the Duracon® femoral and tibial 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) Duracon® Metal-Backed Patella (Howmedica) and 4) Kinemax® All Plastic 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 lateral stability testing were presented.

For information, contact: Margaret F. Crowe
Manager, Regulatory Affairs
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
(201) 507-7431
Fax: (201) 507-6870