

K960976  
510(k) Summary

AUG - 7 1996

Proprietary Name: Kinematic® II Replacement Tibial Inserts

Common Name: Tibial Insert - Total Knee System

Classification Name and Reference: 21 CFR 888.3560  
Knee joint patellofemorotibial polymer/metal/polymer  
semi-constrained cemented prosthesis

Proposed Regulatory Class: Class II

Device Product Code: JWH OR(87)

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

The Kinematic® II Replacement Tibial Inserts are intended to be used in the revision of an existing Kinematic® II tibial component assembly. These inserts are intended to be used when the Vitallium baseplate portion of the tibial assembly is well fixed by cement, but the polyethylene bearing portion of the tibial assembly needs revision due to wear or ligament laxity.

The Kinematic® II Replacement Tibial Inserts are equivalent to other legally marketed devices in commercial distribution. These devices are:

1. Kinematic® II Condylar Cruciate Retaining Tibial Component - Howmedica (K823420)
2. Kinematic® II Total Condylar Tibial Component - Howmedica (K823420)
3. Kinematic® II Stabilizer Tibial Component - Howmedica (K823420)
4. P.C.A. Primary Tibial Inserts for Duracon® Baseplates - Howmedica (K936008)
5. P.C.A. Modular Tibial Inserts for Duracon® Baseplates - Howmedica (K940861)

This equivalence is based upon similarities in intended use, material, and design to the legally marketed devices. Testing was presented which characterized the contact area and range of constraint for the subject devices, and the attachment strength of the inserts to the baseplates. Comparisons were made to legally marketed devices.