

In accordance with the Food and Drug Administration Interim Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Natural-Knee® Tibial Baseplates and the Natural-Knee® All Poly Patella.

Submitter: Intermedics Orthopedics®, Inc.
1300 East Anderson Lane
Austin, Texas 78752
(512) 835-1971

Date: September 29, 1993

Contact Person: JoAnn Ringer
Manager, Regulatory Affairs

Classification Name: Knee Joint Patellofemorotibial
Polymer/Metal/Polymer Semi-Constrained
Prostheses

Common/Usual Name: Total Knee Replacement, Tibial Articulating
Surface

Trade/Proprietary: Natural-Knee® Tibial Baseplates
Natural-Knee® All Poly Patella

PRODUCT DESCRIPTION/SUBSTANTIAL EQUIVALENCE:

Tibial Components

The Natural-Knee® Tibial Baseplates involve modifications to the original Natural-Knee® Tibial Baseplates. The modifications to the tibial resurfacing and stemmed baseplates involve the addition of a centrally located screw hole for optional enhanced insert/baseplate fixation. Furthermore, changes to the configuration of the porous coating pockets and increase in overall baseplate thickness were made to the resurfacing baseplate. The Natural-Knee® Baseplates are semi-constrained in design and both the medial and lateral collateral ligaments must be intact. The tibial baseplates are part of the present Natural-Knee® System and mate with the same Natural-Knee® tibial inserts as the existing Natural-Knee® tibial baseplates. The inferior surface of the porous-coated baseplate is coated with Cancellous Structured Titanium (CSTi™).

The design is substantially equivalent to the tibial baseplates used in the Kirschner™ Performance™ Knee and the Biomet AGC Knee in that both of the baseplates have centrally located screw holes for tibial tray fixation. The tibial plateau is cruciate retaining as is the Howmedica P.C.A. and the Zimmer Miller-Galante Knee System.

Results of an analysis indicated that the baseplate would withstand acceptable cantilever fatigue loading conditions.

Patella

The Natural-Knee All Poly Patella is designed to articulate with the Natural-Knee® Primary and Revision femoral components. It has a circular shape and is provided in 4 sizes and thicknesses of 7 and 10mm. The design is similar to the Richards® Genesis Knee All-Poly Patellae.

Patello-femoral contact area and lateral subluxation tests were performed. The results of these tests are comparable to competitive all poly patellas.