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510(k) SUMMARY

December 14, 1995

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 510(k) Summary for the Intermedics Orthopedics, Inc. Natural-Knee• II - Unicompartmental Knee System.

Submitter:	Intermedics Orthopedics, Inc. 9900 Spectrum Drive Austin, TX 78717 (512) 432-9687
Contact Person:	Jacquelyn Hughes Manager, Regulatory Affairs
Classification Name:	Knee joint femorotibial metal/polymer semi-constrained cemented prothesis, 21 CFR 888.3530.
Common/Usual Name:	Unicondylar knee prosthesis, partially constrained
Trade/Proprietary:	Natural-Knee• II - Unicompartmental Knee Prosthesis

Product Description/Substantial Equivalence:

The Natural-Knee II - Unicompartmental Knee Prosthesis is intended for resurfacing of one side of the knee joint. The system consists of metallic femoral and tibial components as well as a polyethylene tibial insert.

The femoral component is a symmetrically designed component, eliminating the need for left/right orientations. The femoral component is manufactured from cast cobalt chromium/molybdenum (CoCrMo) and features a central cruciate stem which aids in stabilization. A central posterior runner is incorporated into the inner surface to provide further rotational stability. Contact area is maximized by the "sweeping" condylar geometry. Both a nonporous and CSTi porous coated version are available. The femoral component is available in 7 sizes (1-7).

The tibial component is a symmetrically designed component, eliminating the need for left/right orientations. The tibial component is manufactured from wrought titanium alloy (Ti-6Al-4V). The baseplate features three pegs on the underside which aid in rotational stabilization. A screw hole has been placed in the center of the baseplate for optional screw fixation. The baseplate is designed with capture features which permit the UHMWPE tibial insert to be snapped into place. Both a nonporous and CSTi porous coated version are available. The baseplate is available in 6 sizes (1-6).

The tibial insert is a symmetrically designed component manufactured from Ultra-High Molecular Weight Polyethylene (ASTM F648). The insert articulating geometry is semi-constrained and is captured in the baseplate by the mating capture features. The insert is available in 3 thicknesses (9, 11, and 13 mm) and 3 sizes (1-2, 3-4, and 5-6).

Contact area and constraint testing on the femoral and tibial components showed the Natural-Knee II Unicompartmental Knee Prosthesis to be comparable to other legally marketed devices.

Testing on the baseplate-insert locking mechanism indicated that the push-out strength was comparable to other legally marketed devices.

The Natural-Knee II Unicompartmental Knee Prosthesis is also similar to the Howmedica PCA Unicompartmental Knee System, the DePuy Synatomic Unicondylar Knee, the Wright Medical Whiteside Ortholoc II Unicondylar Knee System, the Osteonics Omnifit SCR Knee System, the Zimmer Miller/Galante Unicompartmental Knee System, the Kirschner Performance Unicompartmental Knee, the Smith & Nephew Richards Genesis Unicompartmental Knee, and the Johnson & Johnson PFC Unicompartmental Knee System.