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ATTACHMENT VII

Summary of Safety and Effectiveness
510(k) SUMMARY
Consensus® Posterior Stabilized Knee-
Intercondylar Notch Router

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Trade Name: Consensus® Posterior Stabilized Knee-
Intercondylar Notch Router

Common Name: Intercondylar Notch Router

Classification Name:

Substantial Equivalence:

Whiteside ORTHOLOC II Posterior Stabilized End Mill and Template

Intermedics Orthopedics® Natural Knee II System Posterior Stabilized Router
Assembly

Device Description: A template is placed on the distal femur. This template is made from stainless steel (17-4PH SS @ H900). The template contains a central groove with adequate markings that ensure proper guidance of the router.

The router itself consists of a router bit (17-4PH SS @ H900), the shank of which is encased in a plastic body (Ultem® 4000) that acts as a handle for the surgeon and as a journal bearing for the shaft of the router bit.

The base of the body has a large diametrical flange that rests on the superior surface of the template. This flange acts to stabilize the router against torsional forces created by the router bit. The superior end of the router shank is attached to a standard flexible shaft. A standard Zimmer fitting is integrally machined to the superior side of the flexible shaft in order to accommodate a standard operating room power drill (Stryker, 3M, etc.).

The router body and bit are available in one size. The template is available in three sizes; size 1/2, size 3/4, and size 5/6. This accommodates the range of Consensus® Knee posterior stabilized femoral components.

Intended Use: The Consensus® Posterior Stabilized Knee system employs a router device to remove the intercondylar bone from the distal portion of the femur. This bone must be removed to accommodate the spine of the posterior stabilized tibial insert. This procedure occurs after all bone resections of the distal femur have been completed in the traditional manner with the existing Consensus® Knee instruments.

Summary of Technological Characteristics:

Summary of Risk Analysis: The risk analysis showed that none of the possible failure modes resulted in a risk index greater than 10. According to the scale, no additional action is required to address risk and/or hazards resulting from the use of this device. Preventative measures that are incorporated into the design are shown on the risk analysis of Section ____

Performance Data: No performance data exists for this device.

Clinical Data: None Required

Conclusions from Non-clinical and Clinical Data: None Required

Other Necessary Information: None Required