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ATTACHMENT 8 amended 17 Oct 1995

Summary of Safety and Effectiveness

510(k) SUMMARY

**US MEDICAL PRODUCTS, INC.
CONSENSUS® KNEE ALL POLY TIBIA**

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Trade Name: Consensus® All Poly Tibia

Common Name: All Poly (UHMWPE) tibial baseplate knee prosthesis

Classification Name: Prosthesis, knee, patello/femorotibial, semi-constrained, cemented, polymer/metal/polymer, under classification 21CFR888.3560.

Substantial Equivalence: equivalent All poly tibia components are as follows:

Howmedica Duracon All Plastic Tibial component	K922048	SE Sep 8, 1992
Intermedics Orthopedics All-Poly Tibia	K923443	SE 3-31-93
Johnson&Johnson PFC All Plastic Tibia	K910563	SE 5-23-91

Device Description: The Consensus® Knee All Poly Tibia component is manufactured from ultra-high molecular weight polyethylene (ASTM F648). It is a symmetric cruciate-retaining tibial component and is designed to articulate with the Consensus® Knee primary femoral component. Therefore, it has articulating surface geometry similar to the Consensus® Knee congruent tibial insert component. The inferior surface of each component employs dovetail grooves for macro-cement interdigitation between the implant and the bone. Each component has two titanium X-Ray markers for post-operative evaluation: one placed vertically in the distal end of the stem, and one placed horizontally in the central anterior aspect of the component. The design is available in six sizes and each size is available in five thicknesses. The minimum thickness of polyethylene under the articulating surface is 7.5mm for all sizes. The Consensus® All Poly Tibia will be provided sterile.

The Consensus® All Poly Tibia is designed for use with the following Consensus® Total Knee System components:

Consensus® Nonporous CoCr Femoral component
Consensus® Porous CoCr Femoral Component
Consensus® Patellar component, All Polyethylene
Consensus® Patellar component, Titanium/Polyethylene

Intended Use: The Consensus® All Poly Tibia is indicated for use in:

1. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis.
2. Failed osteotomy or unicompartmental replacements
3. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.

Summary of Technological Characteristics: The Consensus® All Poly Tibia is a symmetric UHMWPE cruciate-retaining tibial component designed to articulate with the Consensus® Knee primary femoral component. The inferior surface employs dovetail grooves for macro cement interdigitation. Each component has two titanium X-Ray markers, and is available in six sizes, each in five thicknesses, minimum 7.5mm articulating surface thickness.

Performance Data: The device performs with substantial equivalence to predicate devices.

Clinical Data: None Required

Conclusions from Non-clinical and Clinical Data: The Consensus® All Poly Tibia is substantially equivalent to predicate devices.

Other Necessary Information: None Required