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ATTACHMENT 8

Summary of Safety and Effectiveness

510(k) SUMMARY

US MEDICAL PRODUCTS, INC.
CONSENSUS® Posterior Stabilized Knee System

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Trade Name: Consensus® Posterior Stabilized Knee prosthesis

Common Name: Posterior cruciate ligament sacrificing knee prosthesis; PS Knee

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

Substantial Equivalence: equivalent Posterior Stabilized Knee components:

Johnson&Johnson PFC® Modular Knee System, K884796, SE 03-29-89.

Device Description: The Consensus® PS Knee tibial insert component is manufactured from ultra-high molecular weight polyethylene (UHMWPE, ASTM F648), and is designed to articulate with the Consensus® PS femoral component. The insert has a spine on the central eminence which engages the crossbar of the PS femoral component. The spine is positioned so that the crossbar of the PS femoral component engages at approximately 65° flexion. The inferior surface of each component employs dovetail grooves for positive interlocking with the Consensus® Primary Knee tibial baseplate. The design is available in three sizes and each size is available in five thicknesses.

The Consensus® PS Femoral component is made of CoCrMo alloy (ASTM F75). Both the outer articulating surface and the inner box geometry of the Consensus® PS femoral component are identical to the respective surfaces of the Consensus® Primary Knee femoral component. Therefore, the PS femoral component contains the same deepened

patella groove as the Consensus® Primary Knee femoral component for increased range of motion, utilizes the same instrumentation as the Consensus® Knee for preparing the distal femur, and employs smooth distal pegs for added Medial/Lateral stability. The Consensus® PS femoral component has a shortened patella groove to accommodate the spine of the Consensus® PS tibial insert. It also contains a stabilizing bar located between the posterior condyles which engages the spine of the Consensus® PS tibial insert at high flexion angles.

The Consensus® Posterior Stabilized Knee System will be provided sterile.

The Consensus® Posterior Stabilized Knee is designed for use with the following Consensus® Total Knee System components:

- Consensus® All Poly or metal back Patellar component
- Consensus® Porous Titanium Stemmed Tibial Baseplate
- Consensus® Nonporous Titanium Stemmed Tibial Baseplate
- Consensus® CoCr Stemmed Tibial Baseplate

Intended Use: The Consensus® Posterior Stabilized Knee is indicated for use in:

1. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis in the absence of the posterior cruciate ligament.
2. Failed osteotomy or unicompartamental replacements
3. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.

Summary of Technological Characteristics: The Consensus® PS Tibial Insert is an asymmetric UHMWPE cruciate-sacrificing tibial component designed to articulate with the Consensus® PS Femoral component, and the Consensus® Primary Knee patellar components. The inferior surface of the tibial component employs dovetail grooves for positive interlocking with the tibial baseplate. The design is available in three sizes and each size is available in five thicknesses. The PS Femoral component is asymmetric, with a shortened patella groove to accommodate the spine of the PS tibial insert, and contains a stabilizing bar located between the posterior condyles which engages the spine of the PS tibial insert. It is available in six sizes.

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

Clinical Data: None Required

Conclusions from Non-clinical and Clinical Data: The Consensus® PS Knee is substantially equivalent to the predicate device.

Other Necessary Information: None Required