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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration 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 Modular Options for Severe bone loss and Trauma (MOST) System.

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Contact Person:	Jacquelyn Hughes Manager, Regulatory Affairs
Classification Name:	Knee joint femorotibial metal/polymer constrained cemented prosthesis 21CFR 888.3510 Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis 21CFR 888.3353
Common/Usual Name:	Hinge Knee for Total Knee Replacement/Hip Stem for Total Hip Replacements/Total Hip and Knee Replacement
Trade/Proprietary Name:	Modular Options for Severe bone loss and Trauma (MOST) System

PRODUCT DESCRIPTION

The Modular Options for Severe bone loss and Trauma (MOST) System will be used for the replacement of the proximal, distal or total femur. Replacement of the distal femur would also include replacement of the proximal tibia and the possible resurfacing of the patella, if necessary. Unlike primary hip and knee systems, this system will be used where the amount of femoral resection and restoration required is extreme (e.g., in oncology cases). The modularity of this system allows for the resection of varying amounts of the femur (and the proximal tibia and patella, if necessary) before implantation. A total replacement is possible in those cases where no part of the femur can be salvaged. The components of the MOST System include:

- the proximal femoral replacement that is available in two designs to address the presence or absence of the greater trochanter, with suture holes for soft tissue attachment;
- the distal femoral replacement which mates with a tibial component via a hinge-type mechanism, allowing 15 degrees of internal and external rotation;
- intramedullary (I/M) stems with Cancellous Structured Titanium™ (CSTi™) and femoral segments which will be used in conjunction with the proximal and distal replacements, and,
- an all-poly patella.

DIAGNOSTIC INDICATIONS

This device is intended to replace the proximal, distal or total femur, especially in cases that require extensive resection and restoration. Replacement of the distal femur would also include replacement of the proximal tibia and the possible resurfacing of the patella, if necessary. Proximal replacement components are available for press-fit or cemented application. Components used for replacement of the distal femur are for cemented use only. Specific diagnostic indications for use of the MOST include:

- metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur;
- revision cases requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur; and,
- severe conditions of inflammatory or noninflammatory degenerative joint disease that require extensive resection(s) and replacement(s) of the proximal and/or distal femur.

SUBSTANTIAL EQUIVALENCE

The MOST System is substantially equivalent to products offered by Wright Medical Technology, Inc., Waldemar Link, Joint Medical Products Corporation and Howmedica, Inc. The Segmented Oncology System (S.O.S.™) Proximal Femur (Wright Medical) and the MP Reconstruction Prosthesis (Link) are both modular stem designs which allow for necessary length adjustment. This provides surgeon's with intraoperative flexibility in a variety of clinical situations.

The Hinge-Type Knee of the MOST System is substantially equivalent to the Noiles Total Knee Prosthesis (Joint Medical Products Corporation) and the Kinematic II Rotating Hinge (Howmedica).