

K960626

## 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 Oncology System Technology (MOST).

**Submitter:** Intermedics Orthopedics, Inc.  
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**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 Oncology System Technology (MOST)

### PRODUCT DESCRIPTION/SUBSTANTIAL EQUIVALENCE

The Modular Oncology System Technology (MOST) 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. The components of the MOST include:

- a proximal femoral replacement available with or without Cancellous-Structured Titanium™ (CSTi™),
- suture holes on the Proximal Femur provide for soft tissue attachment, if necessary,
- intramedullary stems with CSTi and femoral segments which will be used in conjunction with the proximal and distal replacements,
- the distal femoral replacement which mates with a tibial component via a hinge-type mechanism, and
- an all-poly patella.

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The Modular Oncology System Technology 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).

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