

**510(k) SUMMARY**

NOV 14 1997

K973087

August 13, 1997

In accordance with the Food and Drug Administration Interim Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a 510(k) summary for the Sulzer Orthopedics Inc. MOST (Modular Options for Severe Bone Loss and Trauma) System Hex I/M Stem.

**Submitter:** Sulzer Orthopedics Inc.  
9900 Spectrum Drive  
Austin, TX 78717  
(512)432-9900

**Contact Person:** Jacquelyn Hughes  
Manager, Regulatory Affairs

**Classification Name:** 21CFR 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis  
  
21CFR 888.3510 - Knee joint femorotibial metal/polymer constrained cemented prosthesis

**Common/Usual Name:** Cemented stem for modular trauma or oncology applications

**Trade/Proprietary Name:** MOST Hex Intramedullary (I/M) Stem

**PRODUCT DESCRIPTION:**

The MOST System is used for the replacement of the proximal, distal and/or total femur. Unlike primary hip and knee systems, this system is used where the amount of femoral resection and restoration required is extreme (e.g., in oncology cases). A total replacement is possible in those cases where no part of the femur can be salvaged.

The Hex I/M stems are hex shaped and designed to serve as the modular stem portion of either the proximal or distal femoral replacement. A taper feature at the end of the stem allows for connection to the mating modular component. The hex shape allows for rotational stability within the femoral canal once the stem is cemented into place. A ring of CSTi coating around the neck of the CoCr stem (ASTM F1537) allows for tissue attachment.

### **SPECIFIC DIAGNOSTIC INDICATIONS:**

The MOST System is intended to replace the proximal, distal and/or total femur, especially in cases that require extensive resection and restoration. The Hex I/M Stem is intended for cemented use only in these situations. Specific diagnostic indications for use of the MOST System 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;
- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement of the proximal and/or distal femur;
- patients suffering from severe arthropathy of the hip and/or knee that does not respond to any conservative therapy or better alternative surgical treatment;
- revision cases requiring extensive resection(s) and replacement(s) of the proximal, distal, or total femur.

### **SUBSTANTIAL EQUIVALENCE:**

Substantial equivalence determination is based on comparison of the MOST Hex I/M Stem to the following legally marketed predicate competitive devices:

- Sulzer Orthopedics MOST System
- Wright Medical Segmented Oncology System (S.O.S.)
- Waldermar Link MP Reconstruction Prosthesis
- Johnson & Johnson/Joint Medical Products Noiles Knee System
- Howmedica Kinematic II Rotating Hinge Knee System



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mitchell A. Dhority, RAC  
Senior Regulatory Affairs Specialist  
Sulzer Orthopedics, Inc.  
9900 Spectrum Drive  
Austin, Texas 78717

NOV 14 1997

Re: K973087  
Trade Name: MOST System Hex Intramedullary (I/M) Stem  
Regulatory Class: II  
Product Codes: JDI, LZO, and KRO  
Dated: August 14, 1997  
Received: August 18, 1997

Dear Mr. Dhority:

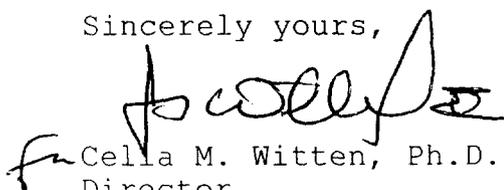
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Cella M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K973087

Device Name: Modular Options for Severe Bone Loss or Trauma (MOST) - Hex I/M Stem

**Indications for Use:**

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- 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;
- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement of the proximal and/or distal femur;
- patients suffering from severe arthropathy of the hip and/or knee that does not respond to any conservative therapy or better alternative surgical treatment;
- revision cases requiring extensive resection(s) and replacement(s) of the proximal, distal, or total femur.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K973087

Prescription Use  OR Over-the Counter Use

(Optional Format 1-2-96)