510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

JAN - 9 2008

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the REPIPHYSIS® Limb Salvage Proximal Femur and Total Femur.

Submitted By:	Wright Medical Technology, Inc.
Date:	June 27, 2007
Contact Person:	Ehab Esmail Director, Regulatory Affairs
Proprietary Name:	REPIPHYSIS® Limb Salvage Proximal Femur and Total Femur
Common Name:	Limb Salvage System
Classification Name and Reference:	21 CFR 888.3510 Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer – Class II 21 CFR 888.3350 Prosthesis, Hip, Semi-Constrained, Metal/Polymer Cemented– Class II
Device Product Code and Panel Code:	Orthopedics/87/JDI Orthopedics/87/KRO

DEVICE INFORMATION

A. INTENDED USE

The REPIPHYSIS Limb Salvage Proximal Femur and REPIPHYSIS Limb Salvage Total Femur are indicated for cemented procedures where radical resection and replacement of the proximal or total femur is required in skeletally immature patients (weighing up to 67 lbs) with osteosarcoma.

REPIPHYSIS Limb Salvage Proximal and Total Femur devices are intended for cemented use only.

B. DEVICE DESCRIPTION

The REPIPHYSIS® Limb Salvage Proximal Femur is designed to replace the proximal femur with an expansion mechanism that has the identical internal components as the expansion mechanism in the previously cleared REPIPHYSIS® Limb Salvage System. The REPIPHYSIS® Limb Salvage Total Femur is designed to replace the entire femur with an expansion mechanism in the distal femoral portion that is identical to the expansion mechanism in the previously cleared REPIPHYSIS® Limb Salvage System.

REPIPHYSIS® Limb Salvage Proximal Femur

The REPIPHYSIS® Limb Salvage Proximal consists of a femoral stem, a femoral housing with expansion mechanism, and a femoral neck designed to be used with all previously cleared WMT 12/14 taper femoral heads. The components of the REPIPHYSIS® Proximal Femur are substantially equivalent to the components of the GUARDIAN™ Limb Salvage System for proximal femur replacement. The REPIPHYSIS® Limb Salvage Proximal Femur is custom assembled for each patient.

REPIPHYSIS® Limb Salvage Total Femur

The REPIPHYSIS® Limb Salvage Total Femur consists of a tibial base, axial bushing, axial pin, distal hinge femur housing with expansion mechanism, and a proximal femoral component. The components of the REPIPHYSIS® Total Femur are substantially equivalent to the components of the GUARDIAN™ Limb Salvage System for total femur replacement. The tibial base, axial bushing, axial pin, and distal hinge femur housing with expansion mechanism are identical to the components of the REPIPHYSIS® Limb Salvage System. The REPIPHYSIS® Limb Salvage Total Femur is custom assembled for each patient.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The material and design features of the proposed REPIPHYSIS® Proximal Femur and Total Femur are substantially equivalent to the REPIPHYSIS® Limb Salvage System. The surgical technique and intended use for the REPIPHYSIS® Proximal Femur and Total Femur are substantially equivalent to the GUARDIAN™ Limb Salvage System. The safety and effectiveness of the REPIPHYSIS® Limb Salvage Proximal Femur and Total Femur are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2008

Wright Medical Technology, Inc.
% Mr. Ehab M. Esmail
Director, Regulatory Affairs
5677 Airline Road
Arlington, Tennessee 38002

Re: K072367
Trade/Device Name: REPIPHYSIS® Limb Salvage System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO, JDI
Dated: December 18, 2007
Received: December 28, 2007

Dear Mr. Esmail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072367

Device Name: REPIPHYSIS® Limb Salvage System

Indications For Use:

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REPIPHYSIS Limb Salvage Proximal and Total Femur devices are intended for cemented use only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072367