WRIGHT
MEDICAL TECHNOLOGY, INC.
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ARLINGTON, TN 38002
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K021489
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DEC 0 4 2002

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 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the REPIPHYSIS™ Limb Salvage System.

Submitted By:	Wright Medical Technology, Inc.
Date:	May 7, 2002
Contact Person:	Ehab M. Esmail Manager, Regulatory Affairs
Proprietary Name:	REPIPHYSIS™ Limb Salvage System
Common Name:	Limb Salvage System
Classification Name and Reference:	21 CFR 888.3510 Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer – Class II
Device Product Code and Panel Code:	Orthopedics/87/ KRO

DEVICE INFORMATION

A. INTENDED USE

The REPIPHYSIS™ prosthesis is indicated for cemented procedures where radical resection and replacement of the distal femur and/or proximal tibia is required with the following conditions:

1. patients suffering from severe arthropathy of the knee that does not respond to any conservative therapy or better alternative surgical treatment;
2. surgical intervention for severe trauma, revision knee arthroplasties, and/or oncology indications.
3. metastatic diseases (e.g., osteosarcomas, chondrosarcomas, gaint cell tumors, bone tumors)

The REPIPHYSIS™ Limb Salvage System components are for single use only.

B. DEVICE DESCRIPTION

BACKROUND DESCRIPTION

Malignant bone tumors in children often occur in the long bones, at or near the joints (shoulder, hip, and knee). Removal of the tumor often requires removal of part or the entire joint. Because the joint is where the growth of the limb occurs, one of the major problems in saving the limb in young growing children involves the ability to maintain equal lengths of the operated arm or leg with the unoperated side. Many attempts have been made to design a prosthesis, which could be easily expanded either without surgery or through a very minor surgical procedure. Most of these designs have had mechanical difficulty or the lengthening procedure becomes a major surgical effort. The REPIPHYSIS™ Limb Salvage System the complications that are known to occur with repeated operations. Once the prosthesis is fully implanted, the noninvasive lengthening of the prosthesis is activated by an external electromagnetic field.

The REPIPHYSIS™ Limb Salvage System (Wright Medical Technology, Arlington, Tennessee) was previously named the Phenix Growing Prosthesis (Phenix Medical, Paris, France). The Phenix Growing Prosthesis was designed in France in the early 1980s. More than 100 patients have been treated with Phenix Growing Prosthesis in the last 20 years.

IMPLANT DESCRIPTION

The REPIPHYSIS™ Prosthesis is custom assembled for each patient. The REPIPHYSIS™ is implanted the same way as any other joint replacement device using non-allergic, standard materials that have been tested in biological situations. The REPIPHYSIS™ Limb Salvage Prosthesis Kit consists of the following components:

Distal Hinge Femur

The femoral housing is the main body of the distal hinge femoral portion of the implant. The most distal end of the femoral housing forms the outer components of the femoral-tibial hinge. It internally houses the following various components of the expansion mechanism.

Tibial Base

The tibial base provides fixation to the proximal tibia. It consists of a cylindrical stem portion, which extends into the proximal tibial medullary canal. The more proximal portion of the tibial base has a flat plate that rests on the patient's tibial plateau region. On the underside of this plate are two small tabs that protrude down into the tibial plateau for rotational stability. On the top of this plate is the inner component of the femoral-tibial hinge mechanism.

Axial Bushing

The axial bushing goes inside the center hinge portion of the tibial base. This bushing is held in place by the two outer hinge features of the femoral housing. This bushing supplies the wear surface through which forces are transmitted between the femoral and tibial components and around which rotation occurs.

Axial Pin

The axial pin is introduced through the outer hinge portion of the distal femoral housing and into the axial bushing, which is contained in the center hinge portion of the tibial base. It extends through the other side of the outer hinge mechanism of the femoral housing. The axial pin mates with the outer hinge portions of the distal femoral housing and the inner diameter of the axial bushing. The axial pin is the pivot for the femoral-tibial hinge mechanism.

INSTRUMENT DESCRIPTION

The REPIPHYSIS™ prosthesis is implanted the same way as any other Limb Salvage System.

In addition the REPIPHYSIS™ prosthesis uses an external electro-magnetic transmitter to activate the implant lengthening mechanism. The REPIPHYSIS Transmitter Unit operates by producing an electrical current in an inductor coil, which in turn generates a strong electro-magnetic field in the vicinity of the coil. When an electrically conductive material is placed within this electro-magnetic field, an electrical current is induced in the conductive material. If the proper conditions are established, this electrical current is sufficient to cause significant heating in this material.

OPERATION DESCRIPTION

The REPIPHYSIS™ prosthesis is implanted the same way as any other Limb Salvage System.

The lengthening technique for the REPIPHYSIS™ prosthesis is briefly described below:

The REPIPHYSIS™ prosthesis consists of two tubes with a spring mechanism contained in the larger tube (Exhibit 11: Photo of the Femoral Housing and sub-components). It is maintained compressed by a polyacetal locking mechanism. One tube is connected to the stem of the implant, and the second comprises the hinge portion of the hinge prosthesis. The uninvolved side of the joint is minimally resurfaced with a press-fit stem to attempt to preserve function of the non-involved growth plate. Expansion is achieved via exposure to an external electromagnetic field around the extremity. The coil transmits an electromagnetic field around the implant in the vicinity of the v-shaped flange of the spring housing tube. This generates an electrical current within the flange of the spring housing tube and is focused on the receiving antennae within the implant itself. This antenna is heated by the electromagnetic field. The heated element softens the surrounding polyacetal locking mechanism, which allows the spring expansion. The spring expansion pushes the two tubes apart from each other, thus lengthening the overall length of the leg. As skeletal growth occurs on the contralateral side, a discrepancy in the overall length of the two legs occurs. Follow-up scanograms quantify the discrepancy. Once a .5- to 1.0-cm discrepancy has occurred, the patient is taken to the fluoroscopy suite and remains awake without sedation or anesthesia. The receiving antennae within the implant are identified under fluoroscopy guidance and the skin is marked. The electromagnetic device is then applied over the receiving antennae, and the patient

activates the device for a period of approximately 15 seconds. A radiograph using magnification markers is then obtained of the level of the spring to determine how much lengthening has occurred. Once the desired amount of lengthening (typically 0.5 to 1cm) is achieved, the process is stopped. One or two activation processes are required to achieve the desired lengthening. The procedure is halted if the patient experiences any discomfort or anxiety. Follow-up radiographs are scheduled at 2 to 3-month intervals until the next lengthening is required.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, type of interface, and design features of REPIPHYSIS™ Limb Salvage System are substantially equivalent to the competitive devices previously cleared for market. The safety and effectiveness of the REPIPHYSIS™ Limb Salvage System are adequately supported by the substantial equivalence information, materials data, and testing results provided within the Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 4 2002

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

Re: K021489
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: Class II
Product Code: KRO
Dated: November 18, 2002
Received: November 19, 2002

Dear Mr. Esmail:

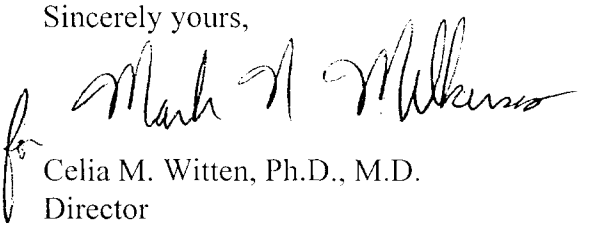
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

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REPIPHYSIS™ Limb Salvage System

INDICATIONS STATEMENT

Limb salvage surgery is indicated for cemented procedures where radical resection and replacement of the distal femur and/or proximal tibia is required with the following conditions:

1. patients suffering from severe arthropathy of the knee that does not respond to any conservative therapy or better alternative surgical treatment;
2. surgical intervention for severe trauma, revision knee arthroplasties, and/or oncology indications.
3. metastatic diseases (e.g., osteosarcomas, chondrosarcomas, gaint cell tumors, bone tumors)

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021489