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DEC 0 7 2001

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

# 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 GUARDIAN™ Limb Salvage System.

| | |
|---|---|
| Submitted By: | Wright Medical Technology, Inc. |
| Date: | September 7, 2001 |
| Contact Person: | Ehab M. Esmail<br>Manager, Regulatory Affairs |
| Proprietary Name: | GUARDIAN™ Limb Salvage System |
| Common Name: | Limb Salvage System |
| Classification Name and Reference: | 21 CFR 888.3350 Prosthesis, Hip, Semi-Constrained, Metal/Polymer Cemented– Class II<br>21 CFR 888.3510 Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer – Class II |
| Device Product Code and Panel Code: | Orthopedics/87/ JDI, KRO |

## DEVICE INFORMATION

### A. INTENDED USE

The indications for use for the GUARDIAN™ Limb Salvage System will be substantially equivalent to the indication for use listed under competitive devices previously cleared for market and identical to the indication for use previously submitted under Lacey Rotating Hinge Knee, DCW Modular Distal Femoral System, and. S.O.S.™ Proximal Femur.

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## GUARDIAN™ Limb Salvage Hip Components:

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and,
5) treatment of fractures that are unmanageable using other techniques.

Limb salvage system is also indicated for procedures where radical resection and replacement of the proximal, distal and/or total femur is required with the following conditions:

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

## The GUARDIAN™ Limb Salvage Knee Components:

Indicated for cemented use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) inflammatory degenerative joint disease including rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and,
5) treatment of fractures that are unmanageable using other techniques.

Limb salvage system is also indicated for procedures where radical resection and replacement of the 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; and,
3) matastatic diseases (e.g., osteosarcomas, chondrosarcomas, gaint cell tumors, bone tumors).

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## B. DEVICE DESCRIPTION

The GUARDIAN™ Limb Salvage System consists of components that are used in the reconstruction of the lower limb. The reconstruction applications are proximal femur, distal femur, total femur, proximal tibia, and hinged knee. The components are femoral neck, mid-section, stem, distal hinge femur, tibial hinge assembly, axial pin, tibial sleeve spacer, tibial sleeve, male-male mid-section, resurfacing hinge femur, and proximal tibia.

| | RECONSTRUCTION APPLICATIONS | | | | |
|---|---|---|---|---|---|
| COMPONENTS | PROXIMAL FEMUR | DISTAL FEMUR | TOTAL FEMUR | PROXIMAL TIBIA | HINGED KNEE |
| FEMORAL NECK | ✓ | | ✓ | | |
| MID-SECTION | ✓ | ✓ | ✓ | ✓ | |
| STEM | ✓ | ✓ | | ✓ | |
| DISTAL HINGE FEMUR | | ✓ | ✓ | | |
| TIBIAL HINGE ASSEMBLY | | ✓ | ✓ | ✓ | ✓ |
| AXIAL PIN | | ✓ | ✓ | ✓ | ✓ |
| TIBIAL SLEEVE SPACER | | ✓ | ✓ | ✓ | ✓ |
| TIBIAL SLEEVE | | ✓ | ✓ | | ✓ |
| MALE-MALE MID-SECTION | | | ✓ | | |
| RESURFACING HINGE FEMUR | | | | ✓ | ✓ |
| PROXIMAL TIBIA | | | | ✓ | |

## C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, type of interface, and design features of GUARDIAN™ Limb Salvage System are substantially equivalent to the competitive devices previously cleared for market. The safety and effectiveness of the GUARDIAN™ 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 7 2001

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

Re: K013035
Trade/Device Name: GUARDIAN Limb Salvage System
Regulation Number: 21 CFR 888.3510; 21 CFR 888.3350
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis; Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO, JDI
Dated: September 7, 2001
Received: September 10, 2001

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 and additionally 21 CFR Part 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" (21CFR 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 Mark N Melkerson

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

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

for Mark N Milleman

(Division) Restorative
Division and Neurological Devices

510(k) Number K01305

K013035

**GUARDIAN™ Limb Salvage System**

# INDICATIONS STATEMENT

**GUARDIAN™ Limb Salvage Hip Components:**
Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and,
5) treatment of fractures that are unmanageable using other techniques.

Limb salvage system is also indicated for procedures where radical resection and replacement of the proximal, distal and/or total femur is required with the following conditions:

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

**The GUARDIAN™ Limb Salvage Knee Components:**
Indicated for cemented use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) inflammatory degenerative joint disease including rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and
5) treatment of fractures that are unmanageable using other techniques.

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Limb salvage system is also indicated for procedures where radical resection and replacement of the 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) matastatic diseases (e.g., osteosarcomas, chondrosarcomas, gaint cell tumors, bone tumors)

(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 _____

Prescription Use X
(Per21 CFR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)

for Mark N. Milhous

**(Division Sign-Off)**
**Division of General, Restorative and Neurological Devices**
**510(k) Number** K013035



WRIGHT MEDICAL TECHNOLOGY
A Wright Medical Group Company