JAN 21 2000 K992403 Weisendorf, November 5th, 1999

Manufacturers name: ROTEC MEDIZINTECHNIK GmbH
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Revised Summary of Safety & Effectiveness
Information Supplied as part of the 510 (k) Application for the
ROTEC MEDIZINTECHNIK GmbH
MRP-Titan System

Proprietary Name: ROTEC, MRP-Titan System

Complete device description:
The patientmatched modular revision hip system MRP-Titan was developed to achieve best fixation of the stem in the femur canal by using a star-shaped design. Depending on the needed length the surgeon is able to decide using the sleeve or not. All necks are available in three sizes to achieve the total length needed. The use of the instruments and the single step to assemble the system is shown very clearly in the enclosed pictures.
The MRP-Titan components are single-use devices.
Identification of all device components, sizes and materials:

Name	Article No.	Diameter/size	Materials
Stem 200 mm, curved	61013-03	13 mm	Ti6Al4V
Stem 200 mm, curved	61014-03	14 mm	Ti6Al4V
Stem 200 mm, curved	61015-03	15 mm	Ti6Al4V
Stem 200 mm, curved	61016-03	16 mm	Ti6Al4V
Stem 200 mm, curved	61017-03	17 mm	Ti6Al4V
Stem 200 mm, curved	61018-03	18 mm	Ti6Al4V
Stem 200 mm, curved	61019-03	19 mm	Ti6Al4V
Stem 200 mm, curved	61020-03	20 mm	Ti6Al4V
Stem 200 mm, curved	61021-03	21 mm	Ti6Al4V
Stem 200 mm, curved	61022-03	22 mm	Ti6Al4V
Stem 140 mm, straight	61013-01	13 mm	Ti6Al4V
Stem 140 mm, straight	61014-01	14 mm	Ti6Al4V
Stem 140 mm, straight	61015-01	15 mm	Ti6Al4V
Stem 140 mm, straight	61016-01	16 mm	Ti6Al4V
Stem 140 mm, straight	61017-01	17 mm	Ti6Al4V
Stem 140 mm, straight	61018-01	18 mm	Ti6Al4V
Stem 140 mm, straight	61019-01	19 mm	Ti6Al4V
Stem 140 mm, straight	61020-01	20 mm	Ti6Al4V
Stem 140 mm, straight	61021-01	21 mm	Ti6Al4V
Stem 140 mm, straight	61022-01	22 mm	Ti6Al4V
Special Implant for Trochanter	61000-04	small	Ti6Al4V
Special Implant for Trochanter	61000-05	large	Ti6Al4V

CE 0197

Neck with Trochanter	61000-11	K	Ti6Al4V
Neck with Trochanter	61000-12	M	Ti6Al4V
Neck with Trochanter	61000-13	L	Ti6Al4V
Locking screw	61000-06		Ti6Al4V
Neck without fin	61002-11	K	Ti6Al4V
Neck without fin	61002-12	M	Ti6Al4V
Neck without fin	61002-13	L	Ti6Al4V
Neck with fin	61001-11	K	Ti6Al4V
Neck with fin	61001-12	M	Ti6Al4V
Neck with fin	61001-13	L	Ti6Al4V
Screw	60901-04	small	Titanium
Screw	60901-07	large	Titanium
Extension sleeve	61016-04	16 mm	Ti6Al4V
Extension sleeve	61018-04	18 mm	Ti6Al4V
Extension sleeve	61020-04	20 mm	Ti6Al4V
Extension sleeve	61022-04	22 mm	Ti6Al4V

Included are **Confidential** Detailed Drawings of the MRP-Titan System

Implant Materials: Medical Alloy Ti6Al4V, ASTM F136
Biolox® forte, (Medical Alumina Al_2O_3), ISO 6474

Statement of Safety: We have reviewed all prior literature on this type of implant device and can not find a substantial body of information on the adverse effects with this device.

Potential Risks:
The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to bone cement	Bone fracture
Fracture of the component	Hematoma
Cardiovascular disorders	Blood vessel damage
Implant loosening/migration	Nerve damage
Soft tissue imbalance	Excessive wear
Deformity of the joint	Infection
Dislocation	Delayed wound healing
Metal sensitivity	

Substantial equivalency: ROTEC MRP-Titan functions in a similar manner as predicted commercially available devices and are equivalent to systems cited in this application (table 2-2 new) especially to Link, Modular Revision Hip Stem, K 955296 or Johnson & Johnson, System S-ROM, K 961 939.

Indications for use: The MRP-Titan system is intended to be used as the proximal part of a hip stem arthoplasty. The indications for use of the MRP-Titan system are revision operations and femur fractures of primary hip operated patients as well as tumour situations at the femur.

The MRP-Titan System is designed and proven to match with the following hip head: Biolox-forte 12/14, manufactured by Ceramtec CE 0044, FDA Master File.
Fatigue testing acc. to ISO 7206-4, -8 has demonstrated that the device with 12/14 taper survived more than 5 x 10^6 cycles without any failure while loaded acc. to ISO 7206.

Sterilization: The MRP-Titan system metal elements and Alumina balls will be shipped in sterile package by Gamma-Radiation, > 25 kGy, by the process shown and validated in chapter 15, truthful and accurate statement is included.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 2000

Dr. -Ing. Ulrich Holzwarth
Head of Quality Assurance
ROTEC MEDIZINTECHNIK GmbH
Am Muhlberg 31
D-91084 Weisendorf
Germany

Re: K992403
Trade Name: MRP-Titan
Regulatory Class: II
Product Code: LZO
Dated: November 12, 1999
Received: November 15, 1999

Dear Dr. -Ing. Ulrich Holzwarth:

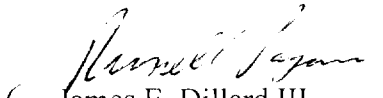
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,



by James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992403

Device Name: MRP-Titan

Indications for use:

- Primary and revision arthroplasty: Revision of primary hip stem prostheses
- Fractures of the proximal femur
- Tumor situation of the proximal femur
- Reconstructions of the upper area of the proximal femur after both primary hip operation or traumafracture
- Recovery of leg-lengthening
- Improving antetorsion after failed primary hip stem operation

Date: 99-11-05

(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 K992403

Prescription Use X OR Over-The-Counter Use___

(Optional Format 1-2-96)

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