Weisendorf, January 25th, 2000

Manufacturers name: ROTEC MEDIZINTECHNIK GmbH
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Contact Person: Dr.-Ing. Ulrich Holzwarth
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FEB 1 8 2000

Revised Summary of Safety & Effectiveness Information Supplied as part of the 510 (k) Application for the ROTEC MEDIZINTECHNIK GmbH MRS-Titan System, K 992359

Complete device description:
The patientmatched modular revision acetabular system MRS-Titan was developed to achieve best fixation of the cup in the acetabulum by using a cementless bone fixation technique. Depending on the needed diameter the surgeon is able to decide the size between ∅ 48 mm and ∅ 64 mm in 4 mm steps. All diameters are able to be used either with a caudal hook and a strap, two straps or only with two straps. In general the caudal hook is designed to fix the original center of rotation because generally the use of MRS-Titan is intended after the second, third or fourth revision operation at the natural acetabulum. Typically this condition shows a very bad boney situation. So this device allows the surgeon to create a good remodelling of the acetabular bone as well as a good mechanical stabilisation of the cup. In comparison to other systems having received the SE-letter the straps are not fixed in one angle, rotation allows to adapt the straps in best angle situation the patient needs.

The MRS components are single-use devices
Identification of all device components, sizes and materials:

Name	Article No.	Diameter/size	Material
Spherical Cup	57348-01	48	Ti6Al4V
Spherical Cup	57352-01	52	Ti6Al4V
Spherical Cup	57356-01	56	Ti6Al4V
Spherical Cup	57360-01	60	Ti6Al4V
Spherical Cup	57364-01	64	Ti6Al4V
Stayhook caudal	57248-01	48	TiRT12
Stayhook caudal	57252-01	52	TiRT12
Stayhook caudal	57256-01	56	TiRT12
Stayhook caudal	57260-01	60	TiRT12
Stayhook caudal	57264-01	64	TiRT12
Staystrap cranial 35 mm	57248-22	48	TiRT12
Staystrap cranial 35 mm	57252-22	52	TiRT12
Staystrap cranial 35 mm	57256-22	56	TiRT12
Staystrap cranial 35 mm	57260-22	60	TiRT12
Staystrap cranial 35 mm	57264-22	64	TiRT12
Staystrap cranial 60 mm	57248-21	48	TiRT12
Staystrap cranial 60 mm	57252-21	52	TiRT12
Staystrap cranial 60 mm	57256-21	56	TiRT12
Staystrap cranial 60 mm	57260-21	60	TiRT12
Staystrap cranial 60 mm	57264-21	64	TiRT12

CE 0197

Name	Article No.	Diameter/size	Material
Countersunk screw	57348-03	M4 x 9,5	Ti6Al4V
Countersunk screw	57348-08	M4 x 12,5	Ti6Al4V
Countersunk screw	57348-28	M4 x 15,5	Ti6Al4V
MC-PE-Insert with snapring	55148-02	48 x 32	UHMWPE
MC-PE-Insert with snapring	55152-02	52 x 32	UHMWPE
MC-PE-Insert with snapring	55156-02	56 x 32	UHMWPE
MC-PE-Insert with snapring	55160-02	60 x 32	UHMWPE
MC-PE-Insert with snapring	55164-02	64 x 32	UHMWPE
MC-PE-Insert with snapring	55148-12	48 x 28	UHMWPE
MC-PE-Insert with snapring	55152-12	52 x 28	UHMWPE
MC-PE-Insert with snapring	55156-12	56 x 28	UHMWPE
MC-PE-Insert with snapring	55160-12	60 x 28	UHMWPE
MC-PE-Insert with snapring	55164-12	64 x 28	UHMWPE
Spongiosascrew	51265-20	6,5 x 20	Ti6Al4V
Spongiosascrew	51265-25	6,5 x 25	Ti6Al4V
Spongiosascrew	51265-30	6,5 x 30	Ti6Al4V
Spongiosascrew	51265-35	6,5 x 35	Ti6Al4V
Spongiosascrew	51265-40	6,5 x 40	Ti6Al4V
Spongiosascrew	51265-45	6,5 x 45	Ti6Al4V
Spongiosascrew	51265-50	6,5 x 50	Ti6Al4V
Spongiosascrew	51265-55	6,5 x 55	Ti6Al4V
Spongiosascrew	51265-60	6,5 x 60	Ti6Al4V

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

Implant Materials: Medical Alloy Ti6Al4V, accord. to ASTM F 136
Ti1, CP Titanium for medical application, accord. to ASTM F 67

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.

Axial and lever arm disassembling (ASTM F 1820) testing results (see item 3 above) showed that there is enough safety regarding the lever arm disassembling force which is double as high as the load of an average human bending. This value covers all diameters and is explained for the smallest and the biggest version in item no. 3. Load values are: *Diameter 48 mm: 1156 N and diameter 64 mm: 1460 N.*

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 sensivity	

Substantial equivalency: ROTEC MRS-Titan functions in a similar manner as predicted commercially available devices and are equivalent to systems cited in this application. (July 1st 1999 and this one). MRS-Titan is substantially equivalent to other acetabular devices on the market in our design and intended function. The following devices are predicated to the MRS-Titan: Osteonics restauration gap, K963946, Biomeds modular acetabular reconstructive system, K 911718, Biomeds recovery protrusio cup, K 971890, Osteonics modular acetabular cup, microstructured version, K 963946, Biomeds modular protrusio cup, K 990032 (here are several different options with the use of a hook and straps).

Indications for use: The MRS-Titan system is intended to be used as the acetabular part of a hip arthroplasty. The indications for use of the MRS-Titan system are revision operations and fractures of primary hip operated patients, especially with large bone defects in the acetabulum, as well as tumour situations at the acetabulum.

The MRS-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, MAF 746. Fatigue testing – using the MRS-Titan while testing hip stems – according to ISO 7206-4 has demonstrated that the device with survived 5 x 10^6 cycles without failure while loaded according to ISO 7206.

Sterilization: The MRS-Titan system metal and Polyethylene will be shipped in sterile package by Gamma-Radiation > 25 kGy, Statement of Truth and Accuracy is included.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 8 2000

Dr. Ing Ulrich Holzwarth
Head of Quality Assurance
Rotec Medizintechnik
Am Muhlberg 31
D-91084 Weisendorf
Germany

Re: K992359
Trade Name: MRS Titan
Regulatory Class: II
Product Code: LZO
Dated: December 10, 1999
Received: January 28, 2000

Dear Dr. 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,

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

Enclosure

510(k) Number (if known): K 992359

Device Name: MRS-Titan

Indications for use:

- Painful, disabling joint diseases of the hip resulting from degeneration, arthritis, rheumatoid arthritis, post traumatic arthritis.
- Revision of previous unsuccessfull femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problem solve arthrodesis or alternative techniques are less likely to achieve satisfactory results.
- Bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated deficiencies of the acetabulum.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992359

Prescription Use X OR Over-The-Counter Use_____

(Optional Format 1-2-96)