APR 1 4 2014

Progress in Surgery

K130778

SECTION 05

510(k) Summary

DATE OF APPLICATION: 2013-04-06

APPLICANT: RZ Medizintechnik
Unter Hasslen 20
78532 Tuttlingen
Germany
Tel.: +49 7461 9470-0
Fax: +49 7461 9470-50
E-Mail: accounting@rz-medizintechnik.com
Internet: www.rz-medizintechnik.com

CONTACT PERSON: Mr. Tobias Zubrod
Tel.: +49 7461 9470-0
E-Mail: tobias.zubrod@rz-medizintechnik.com

1. Device Name

Trade Names: Discoscopes, Cervical Endoscpes
Common Name: Spinal Endoscope
Classification Name: Arthroscope

2. Classification Product Code / Subsequent Code

Device	Medical Specialty	Review Panel	Product Code	Device Class	Regulation Number
Arthroscope	Part 888	Orthopedic	HRX	2	888.1110

3. Prior Submissions

There have been no prior submissions of the subject devices so far.

4. Predicate Device

RZ Medizintechniks Spinal Endoscopes are substantially equivalent to the following predicate devices, already cleared by the FDA:

Predicate Device	510(k) Number	510(k) Holder
THESSYS Multiscope	K051827	Joimax GmbH
Spinal Foraminoscope	K082841	Blazjewski Medi-Tech GmbH

5. Description of the Device

The Cervical Endoscopes of RZ Medizintechnik are optical and fiberoptic-based rigid endoscopes provided with working channels of 2.2mm allowing the insertion of microsurgical instrumentation to perform endoscopic intervention within the cervical spine.

The Discoscopes of RZ Medizintechnik are optical and fiberoptic based rigid endoscopes provided with working channels of 2,8 mm, 3,75 mm and 4,3 mm allowing the insertion of microsurgical instrumentation to perform endoscopic intervention within the spinal column such as endoscopic assisted discectomy.

The Spinal endoscopes of RZ Medizintechnik may be attached to standard fiberoptic lightsources, commonly available video adapters and cameras such as Storz, Olympus and Wolf.

The devices are reusable, delivered in non-sterile conditions and available in various designs:

- Outer Diameters from 3,6 mm to 7,0 mm
- Diameter of working channel from 2,2 mm to 4,3 mm
- Working length from 95 mm to 208 mm
- Direction of view: 0°/6° (cervical endoscope) , 30° (discoscopes)
- Viewing angle 80° +- 5°

6. Indications for Use

The use of RZ Medizintechnik Spinal Endoscopes is indicated for visualization of the intraoperative site during spinal endoscopic procedures and minimally invasive surgery.

7. Technological Characteristics

The technological characteristics of RZ Medizintechnik spinal endoscopes are the same as the previously cleared predicate devices stated in section 3.

8. Testing

Testing in order to proof safety and effectiveness of RZ Medizintechnik Spinal Endoscopes has been performed according to recognized consensus Standards and results are conforming to the respective requirements.

8.1. Thermal Safety

Temperature profile studies according to IEC 60601-2-18 have been conducted in order to provide evidence of sufficient thermal safety of the devices. Results show, that thermal hazards may be excluded if the devices are used according their indications.

8.2. Electrical Safety

The devices subject to this submission have been tested according to the requirements of IEC 60601-2-18. Test setup covered interconnection test and capacitive coupled HF current. Results indicate electrical safety of the devices as required per respective standard.

8.3. Optical Performance

Optical performance of our spinal endoscopes is continuously checked during final inspection of the devices. Every device is checked for optical performance before final release.

8.4. Sterilization

Safety and efficiency of the specified sterilization cycle referenced within the instructions for use has been validated under consideration of the requirements set out in ANSI/AAMI ST81, ANSI/AAMI TIR12, EN ISO 17665 and EN ISO 17664.

8.5. Biocompatibility

The devices have been subjected to biocompatibility testing according to DIN EN ISO 10993-1. Testing has been conducted with greatest challenge devices and provides evidence on acceptable levels of biocompatibility.

9. Substantial Equivalence Summary / Conclusion

Based on available 510(k) information provided herein, RZ Medizintechnik Spinal Endoscopes are considered substantial equivalent to the predicate devices in terms of indications for use, material, technology, design and performance specifications.

There are no differences between the devices which would raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 14, 2014

RZ Medizintechnik GmbH
% Mr. Andre Weingerl
MEDAGENT GmbH & Company KG
Griesweg 47
Muehlheim, Baden-Wuerttemberg 78570
GERMANY

Re: K130778
Trade/Device Name: Discoscopes, Cervical Endoscopes
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: March 3, 2014
Received: March 7, 2014

Dear Mr. Weingerl:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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 Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K130778

Device Name
Discoscopes, Cervical Endoscopes

Indications for Use *(Describe)*
The use of RZ Medizintechnik spinal endoscopes is indicated for visualization of the intraoperative site during spinal endoscopic procedures and minimally invasive surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.04.14 14:45:14 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."