K082902

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

DEC 10 2008

Date: December 2, 2008

Submitter:

Name:	RZ MEDIZINTECHNIK GmbH
Address:	Unter Hasslen 20 78532 Tuttlingen Germany
Contact Person:	Rainer Zubrod
Telephone:	+49.7462.947010
Fax:	+49.7462.947050

Product:

Trade Name:	RZ Endoscopic (Minimally Invasive) Instruments and Accessories
Classification:	Class II
Common Name:	Electrosurgical Instruments and Accessories
Classification Name:	- Electrosurgical Cutting & Coagulation Device & Accessories - Endoscopic Grasping/Cutting Instrument, Non-Powered

Predicate Device: Predicate devices are manufactured by

- Jakoubek Gmbh
- Ackermann Instrumente GmbH
- Gimmi GmbH
- Pajunk GmbH
- Sutter Medizintechnik GmbH
- Guenter Bissinger Medizintechnik GmbH

Device Description: RZ Endoscopic (Minimally Invasive) Instruments and Accessories consist of

1. Modular Forceps (reusable)
2. Single-Piece Forceps
3. Modular Forceps with Disposable Tips
4. Electrodes
5. Resectoscopic Instruments & Electrodes (reusable & disposable)
6. Electrosurgical Cables

Intended Use: RZ Endoscopic (Minimally Invasive) Instruments and Accessories are indicated for various endoscopic procedures and include both electrical and non-electrical accessories.

Performance Data: Testing was performed to support substantial equivalence to the predicate devices. The RZ Endoscopic (Minimally Invasive) Instruments and Accessories met all specified design and performance requirements.

Sterilization The single-use resectoscope electrodes and modular tips are offered sterile by ethylene oxide sterilization.

All remaining devices are offered non-sterile for autoclave

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steam sterilization by user.

Conclusion: Based upon the product technical information provided, intended use and performance information provided in this premarket notification, as well as similarity to legally marketed devices, RZ Endoscopic (Minimally Invasive) Instruments and Accessories have been shown to be substantially equivalent to the current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 2008

RZ Medizintechnik GmbH
% Business Support International
Ms. Angelika Scherp
Amstel 320-I
Amsterdam 1017AP
Netherlands

Re: K082902
Trade/Device Name: RZ Endoscopic (Minimally Invasive) Instruments and Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 29, 2008
Received: September 30, 2008

Dear Ms. Scherp:

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K082902

Device Name: RZ Endoscopic (Minimally Invasive) Instruments and Accessories

Indications for Use: RZ Endoscopic (Minimally Invasive) Instruments and Accessories are indicated for various endoscopic procedures and include both electrical and non-electrical accessories.

Prescription Use __X__ AND/OR **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mkm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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