K073498 p. 1 of 2

K_____ SEP 19 2008

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS IN ACCORDANCE WITH SMDA OF 1990

DATE:
December 5, 2007

Submitted by: RUDOLF MEDICAL GmbH + Co. KG
Zollerstr. 1
D-78567 Fridingen
Germany
Phone: +49 (7463) 9956-0
Fax: +49 (7463) 9956-56
Email: info@rudolf-med.com

1. Device Name

Trade Name: Laparoscopic and Electrosurgical Instruments and Accessories
Common Name: Laparoscopic and Electrosurgical Instruments and Accessories

2. Classification

Our laparoscopic and electrosurgical Instruments can be classified according following Device Names and Product Codes:

Device:	Device, Electrosurgical, Cutting & Coagulation & Accessories
Device description:	Laparoscopic and electrosurgical cutting and coagulation device and accessories.
Medical Specialty:	Part 878, General & Plastic Surgery
Product Code:	GEI
Regulation Number:	878.4400
Device Class:	2

3. Substantial Equivalence

Rudolf's Laparoscopic and Electrosurgical Instruments are substantial equivalent to

- PAJUNK GMBH MEDIZINTECHNOLOGIE, K062047
- GUNTER BISSINGER MEDIZINTECHNIK GMBH, K051429
- GUNTER BISSINGER MEDIZINTECHNIK GMBH, K042077
- ENABLE MEDICAL CORP., K010112
- AESCULAP, INC., K001330

4. Description of the Device

Laparoscopic and electrosurgical instruments are used in various surgical applications. Therefore they are varying in size and build-up, though the general principle remains unchanged.

By using a suitable connecting cable, the monopolar and bipolar instruments can be connected to high-frequency electrosurgical generators.

5. Intended Use

Rudolf's laparoscopic and electrosurgical instruments are designed for dissecting, cutting and optional monopolar or bipolar coagulation of tissue during general surgical procedures.

These devices have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

6. Performance Standards

The devices are conforming to following international standards:

ANSI/AAMI HF18, IEC 60601-1, IEC 60601-1-1, IEC 60601-2-2, IEC 60601-2-18

7. Sterilization

Rudolf's laparoscopic and electrosurgical instruments are supplied non-sterile and must be sterilized before every use by a steam sterilization (pre-vacuum) process at 134°C (273°F) and 5 minutes minimum holding time.

8. Conclusion

Based on the available 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that Rudolf's Laparoscopic and Electrosurgical Instruments are substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2008

Rudolf Medical GmbH & Co., KG
% Medagent GmbH & Co., KG
Mr. Franz Menean
Griesweg 47
Muhlheim, Baden-Wurttemberg
Germany

Re: K073498
Trade/Device Name: Rudolf Laparoscopic and Electrosurgical Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 23, 2008
Received: August 27, 2008

Dear Mr. Menean:

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

K073498 p. 1 of 1

Indications for Use

510(k) Number: K073498

Device Name: **Rudolf Laparoscopic and Electrosurgical Instruments**

Indications for Use:

Rudolf's laparoscopic and electrosurgical instruments are designed for dissecting, cutting and optional monopolar or bipolar coagulation of tissue during general surgical procedures.
These devices have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

Prescription Use __YES___ AND/OR Over-The-Counter Use __NO__
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

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,
and Neurological Devices

510(k) Number K073498