K 060232

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

JUL 12 2006

DATE OF APPLICATION: 2006-01-25

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1. DEVICE DESCRIPTION

Trade Name: electrosurgical instruments and accessories
Common Name: electrosurgical instruments and accessories

2. CLASSIFICATION

Device:	Electrosurgical cutting and coagulation device and accessories
Panel:	878 General and Plastic surgery
Product Code:	GEI
Device Class:	2
Regulation Number:	878.4400

3. INTENDED USE

The Trokamed GmbH Resectoscope & Accessories are indicated for the resection of prostate tissue.
The Trokamed GmbH Monopolar Electrodes are intended for use in minimal invasive techniques where unipolar electrosurgical cutting and coagulation are normally used.
The Trokamed GmbH Bipolar Electrodes are intended for use in minimal invasive techniques where bipolar electrosurgical cutting and coagulation are normally used.
The instruments are reusable; they are intended to be cleaned, sterilized and reused.

4. SUBSTANTIAL EQUIVALENCE

Manufacturer	510(k) Number	Device name
A Richard Wolf	K 973341	Unipolar electrodes
B Valleylab	K 964602	Valleylab coated electrodes
C Megadyne	K 040699	Leris
D Bissinger	K042077	BiTech Bipolar Scissors
E Karl Storz	K960757	Karl Storz Ureter Resectoscope
F COMEG Endoscopy	K 971881	Comeg Resectoscope and...

5. BIOCOMPATIBILITY

The biocompatibility has been approved based on ISO 10993 parts one, five and ten by the accredited Laboratory Bioservice.

6. STERILIZATION BY USER

Trokamed GmbH delivers all unipolar electrodes in Non-Sterile conditions. The user may sterilize these devices by using a validated and applicable sterilization process.
Trokamed GmbH recommends to use a steam-sterilizer that uses a validated sterilization cycle of 134°C / 270°F, 3 bar, for 10 minutes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Trokamed GmbH
% Karlheinz Trondle
General Manager
Kleine Breite 17
78187 Geisingen
Germany

JUL 12 2006

Re: K060232
Trade/Device Name: Electrosurgical instruments and accessories
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulation Class: II
Product Code: GEI
Dated: June 26, 2006
Received: June 28, 2006

Dear Mr. Trondle:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

K060232

Indications for Use

510(k) Number (if known): K060232

Device Name: Electrosurgical instruments and accessories

Indications For Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 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 K060232