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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAR - 1 2011

Date: February 9, 2011

Submitter:

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Product:

Trade Name:	TROKAMED MORCELLATOR
Classification:	HET, GCJ (Class II)
Common Names:	Morcellator
Classification Names:	Endoscopic Cutting Accessory

Predicate Device:

- K993801, Gynecare Laparoscopic Morcellator
- K061180, Storz KSEA Rotocut G1
- K041610, Morce Scope Set – Morcellator
- K960640, S*E*M*M* Set for Moto Drive WISAP

Device Description: The TROKAMED MORCELLATOR is comprised of a control unit, a grip module, two foot pedals, a power cord, a control cable and a flexible shaft, in addition to cutting modules, trocar sheaths, trocars, and forceps.

Intended Use: The TROKAMED MORCELLATOR is a motorized unit for morcellating and extracting tissue during laparoscopic procedures, in general surgery, gynecology including the removal of myomas and hysterectomy, and urology including nephrectomy.

Performance Data: The device complies with applicable requirements of recognized consensus standards IEC 60601-1 (Electrical Safety), IEC 60601-1-2 (Electromagnetic Compatibility) and Medical Device Directive 93/42/EEC, and is manufactured at an ISO 13485 facility.

Sterilization The control unit, power cable and foot pedals are provided non-sterile for disinfection only.

The flexible shaft, control cable, grip module, trocar sheaths, trocars, and forceps are provided non-sterile for steam sterilization.

The cutting modules and the valve unit are provided sterile for single use only.

Conclusion: The basic features, design and intended uses of the TROKAMED MORCELLATOR are similar or identical to those of the predicate devices. The minor differences in design and dimensions have no effect on the performance, function or intended use of the device and do not raise any new issues of safety and effectiveness. In summary, the applicant considers the TROKAMED MORCELLATOR to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Trokamed GmbH
% Ms. Angelika Scherp
Regulatory Affairs Consultant
Business Support International
Amstel 320-I
1017 AP Amsterdam NH 1017AP
THE NETHERLANDS

MAR - 1 2011

Re: K091010
Trade Name: Trokamed Morcellator
Regulation Number: 21 CFR §884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: HET and GCJ
Dated: August 9, 2010
Received: August 19, 2010

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. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K091010

Device Name: TROKAMED MORCELLATOR

Indications for Use: The TROKAMED MORCELLATOR is a motorized unit for morcellating and extracting tissue during laparoscopic procedures, in general surgery, gynecology including the removal of myomas and hysterectomy, and urology including nephrectomy.

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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K091010