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SECTION 5

510(k) SUMMARY
(As required by 21 CFR 807.92)

K082954

OCT 17 2008

5.1 Submitted by

Trod Medical SA
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France

5.2 Contact person

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Regulatory affairs head
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5.3 Date Initial Summary prepared

January 28, 2008

5.4 Name of the device

Proprietary Name: ENCAGE™ bipolar RF probe
Common / Usual name: Hand-held electrosurgical device
Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)

5.5 Predicate devices

- INCIRCLE Bi-Polar RF Ablation device (K070711)
- INTRACEPT Bi-Polar RF Probe and Instrument Set (K070443)
- ATRICURE Bi-Polar coagulation System (K011722)
- RITA STARBURST SDE electrosurgical device (K030967)

5.6 Device description

The ENCAGE™ bipolar RF probe is a sterile, disposable, bi-polar, Radio Frequency (RF), hand-held electrosurgical device that coagulate/ablate a region of soft tissue using bipolar RF energy. The device is designated for use in percutaneous, laparoscopic and intraoperative surgical procedures. The ENCAGE™ bipolar RF probe is used in conjunction with the

Stockert NEURO N50 RF Generator and Interconnect Cables to create radiofrequency lesions in soft tissue.

5.7 Intended Use

The ENCAGE™ bipolar RF probe is intended to be used with the Stockert N50 radiofrequency (RF) generator for the thermal coagulation of soft tissues.

5.8 Comparison of Technological characteristics

The ENCAGE™ bipolar RF probe is substantially equivalent in design, materials, function and intended use to the following devices cleared for commercial distribution:

- INCIRCLE Bi-Polar RF Ablation device (K070711)
- INTRACEPT Bi-Polar RF Probe and Instrument Set (K070443)
- ATRICURE Bi-Polar coagulation System (K011722)
- RITA STARBURST SDE electrosurgical device (K030967)

5.9 Summary of Performance data

The ENCAGE™ bipolar RF probe has been designed to comply with the applicable sections of ANSI/AAMI American Standard for Electrosurgical devices HF-18:2001 and the International Electrotechnical Commission Standard for Electrosurgical devices IEC 60601-2-2:2006. Bench testing/functional testing performed on the ENCAGE™ bipolar RF probe demonstrates that this device is substantially equivalent to the predicate devices. No new safety or effectiveness issues have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Trod Medical SA
% TUV SUD America, Inc.
Mr. Stefan Preiss
1775 Old Highway 8 NW
New Brighton, Minnesota 55112-1891

OCT 17 2008

Re: K082954
Trade/Device Name: ENCAGE™ bipolar RF probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 1, 2008
Received: October 3, 2008

Dear Mr. Preiss:

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

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

Enclosure

SECTION 4

INDICATION FOR USE

510(k) Number (if known): NA K082954

Device Name: ENCAGE™ bipolar RF probe

Indication For Use:

The ENCAGE™ bipolar RF probe is intended to be used in conjunction with radiofrequency (RF) generators for percutaneous, laparoscopic, or intraoperative thermal coagulation of soft tissues.

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)

for mkm

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

510(k) Number K082954