



Food and Drug Administration
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May 28, 2015

TDM SurgiTech Incorporated
% Dr. Linda Braddon, Ph.D.
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K150824

Trade/Device Name: TD-Wand
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 24, 2015
Received: March 27, 2015

Dear Dr. Braddon:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,


Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150824

Device Name

TD-Wand

Indications for Use (Describe)

The TDM SurgiTech TD-Wand is intended for use in procedures that require precise cuts where only light or no hemostasis is desired using the cut mode and procedures where a greater level of hemostasis is desired using the coag and blend modes.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

In accordance with 21 CFR 807.87 (h) and 21 CFR 807.92, the 510(k) summary for the TDM SurgiTech TD-Wand is provided below.

510(k)	K150824
Date Summary Prepared	March 26, 2015
Sponsor	TDM SurgiTech, Inc. Michael Weber 4626 Ayron Terrace Palm Harbor, FL 34685 USA 813-263-5669 (direct) 727-255-5036 (fax) MWeber@TDMsurgiTech.com
510(k) Contact	Secure BioMed Evaluations Linda Braddon, Ph.D. CEO / President 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 (direct) 855-MED-DEV1 (office) LGB@SecureBME.com
Trade Name	TD-Wand
Common Name	Electrosurgical blade
Code –Classification	GEI 21 CFR 878.4400: Class II
Predicate Devices	K960255 Utah Medical Products Inc. Ceramic Blade Electrode
Device Description	<p>TDM SurgiTech, Inc. (“TDMi”)’s TD-Wand is a sterile, single use, disposable, monopolar device for use only with IEC 60601-1 certified electrosurgical units (“ESUs”) that accept 3-pinned connectors. The TD-Wand combines blunt dissection with electrosection and electrocoagulation at its ceramic tip. The ceramic tip’s bulbs provide blunt dissection capabilities between tissue planes similar to a cannula, bulbous scissors, or other blunt instrument. As such, initiation of the dissection path may be facilitated with the use of traditional surgical instruments. The device employs two types of recessed stainless steel electrodes that distribute electrosurgical current:</p> <p>(1) For cutting, the Cutting Electrode is comprised of 3 segments protectively recessed between four ceramic bulbs at the axial tip. When activated, the Cutting Electrode, along its 3 recessed segments, distributes a cut or blended cut/coag waveform yielding a cutting effect that may also have a hemostatic effect depending upon the “blended” waveform chosen.</p> <p>(2) For coagulation, the Coagulation Electrode, via the 7 termini protectively recessed atop the ceramic domes in the chevron shape, distributes coagulation waveforms producing a disbursed surface coagulation effect.</p>

510(k) Summary

Indications for Use	The TDM SurgiTech TD-Wand is intended for use in procedures that require precise cuts where only light or no hemostasis is desired using the cut mode and procedures where a greater level of hemostasis is desired using the coag and blend modes.
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Mechanical Testing

The TD-Wand was tested to determine the performance characteristics of the system. The following tests were performed:

- Static Cantilever Bending
- Static Axial Compression
- Dynamic Compression Bending

The mechanical integrity testing showed the TD-Wand is substantially equivalent to the predicate device.

Electrical Safety Testing

Electrical safety testing was performed on the TDM SurgiTech TD-Wand. Specifically, the following testing was performed to confirm the electrical safety characteristics of the device.

- Medical electrical equipment complies with and was tested with respect to electric shock, fire, electromagnetic compatibility, mechanical and other specified hazards, in accordance with IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007), EN 60601-1:2006, ANSI/AAMI ES60601-1:2005 + A2
- Tested to IEC/EN 60601-1-2 Third Edition (2007-03)
- IEC 60601-2-2: 2009 Particular Requirements for the Basic Safety and Essential Performance of High frequency surgical equipment and high frequency surgical accessories

Thermal Injury Analysis

A comparative analysis of thermal injury created by the TD-Wand versus the predicate Epitome and the ubiquitous paddle electrode was performed. A direct comparison of TD-Wand with other predicate devices showed the thermal zones of the TD-Wand were substantially the same and in many cases not as substantial as those generated by both the Epitome electrode and/or the traditional paddle electrode regardless of tissue type or power setting.

510(k) Summary

K150824

Biocompatibility

Biocompatibility testing in compliance with ISO 10993 showed TDM SurgiTech TD-Wand is fully biocompatible.

Biocompatibility Tests	Results
ISO Cytotoxicity MEM Elution According to ISO 10993-5 Biological evaluation of medical devices: Part 5 Tests for In vitro Cytotoxicity	Cell culture treated with test sample exhibited no reactivity (Grade 0)
Guinea Pig Maximization - Sensitization According to ISO 10993-10 Biological evaluation of medical devices: Part 10 Tests for irritation and delayed hypersensitivity	Albino guinea pigs treated with test sample did not elicit a sensitization response (Grade 0)
Intracutaneous Irritation Reactivity According to ISO 10993-10 Biological evaluation of medical devices: Part 10 Tests for irritation and delayed hypersensitivity	Rabbits treated with test samples were non-irritating (Less than 1.0 difference between test and control)
Pyrogenicity Materials Mediated Rabbit Pyrogen Test	Albino rabbits treated with test samples exhibited a negative response (Max Temperature Increase: 0.1°C) Non-pyrogenic

Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject TDM SurgiTech TD-Wand has been shown to be substantially equivalent to the legally marketed predicate device.