December 20, 2023

Tentech Inc.
% Do Kim
CEO
BT Solutions, Inc.
Unit 904, Eonju-ro 86-gil 5, Gangnam-gu
Seoul, 06210
South Korea

Re: K232992
Trade/Device Name: 10therma
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 22, 2023
Received: September 22, 2023

Dear Do Kim:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.12.20 14:37:59 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K232992

Device Name
10THERMA

Indications for Use *(Describe)*
10THERMA indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

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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# 5. 510(k) Summary

## 5.1 General Information

| | |
|---|---|
| Applicant/Submitter: | Tentech Inc. |
| Address: | 3F, Hyunkyung Building, 611, Seolleung-ro, Gangnam-gu,<br>Seoul, 06103, Republic of Korea |
| Contact Person: | Do Hyun Kim, BT Solutions, Inc. |
| Address: | Unit 904, Eonju-ro 86gil 5,<br>Gangnam-gu, Seoul 06210, Korea.<br>Tel: +82-2-538-9140<br>Email: ceo@btsolutions.co.kr |
| Preparation Date: | September 22, 2023 |

## 5.2 Device Name and Code

| | |
|---|---|
| Device Trade Name: | 10THERMA |
| Model Name: | TMSY02 |
| Common Name: | Electrosurgical Cutting And Coagulation Device And Accessories |
| Classification Name: | Electrosurgical Cutting And Coagulation Device And Accessories |
| Product Code: | GEI |
| Regulation Number: | 21 CFR 878.4400 |
| Classification: | Class II |
| Review Panel: | General & Plastic Surgery |

## 5.3 Technical Characteristics in Comparison to Predicate Devices

The 10THERMA, is substantially equivalent to the following legally marketed predicate device:

| | **Proposed device** | **Primary Predicate Device K170758** |
|---|---|---|
| Applicant | Tentech Inc. | Solta Medical Inc. |
| Device Trade Name | 10THERMA | Thermage FLX System |
| K number | N/A | K170758 |
| Product code | GEI | GEI, ISA |
| Regulation Number | 21 CFR 878.4400 | 21 CFR 878.4400 |

| | | |
|---|---|---|
| Classification Name | Electrosurgical Cutting And Coagulation Device And Accessories | Electrosurgical Cutting And Coagulation Device And Accessories |
| Classification | Class II | Class II |
| Review Panel | General & Plastic Surgery | General & Plastic Surgery |
| Indications for Use | 10THERMA indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. | The radiofrequency-energy only delivery components of the Thermage FLX System are indicated for use in:<br>• Dermatologic and general surgical procedures for electrocoagulation and hemostasis; |
| Output Frequency | 6.78MHz | 6.78MHz |
| Electrode Type | Monopolar | Monopolar |
| Maximum Average Power | 400 W | 400 W |
| Mode of Operation | Manual or footswitch | Manual or footswitch |
| User Interface | LCD / Touchscreen Technology for user interaction and controls | LCD / Touchscreen Technology for user interaction and controls |

**5.4 Device Description**

10THERMA is a High-Frequency Electrosurgical Unit (ESU). When the high-frequency current generated in the main body is transmitted to the skin through the monopolar electrode connected to the handpiece, heat is generated by the electrical resistance of the skin, and tissue is coagulated with the generated heat.

The 10THERMA is comprised of a main body with a touch LCD monitor, a handpiece, non-sterile mono-polar electrodes (handpiece tips), return pads, a return pad connector, coupling fluid, cooling gas (cryogen), a power cable, and a foot switch. Among the consisting items, the mono-polar electrodes, return pads, and coupling fluid are single-use and disposable.

**5.5 Indications / Intended Use**

10THERMA indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

**5.6 Non-Clinical Test Summary**

No clinical studies were considered necessary and performed. The safety and performance of the product were performed. Thus, the proposed device is determined to be as safe, as effective, and performs as well as the legally marketed predicate devices. Please see below.

5.6.1. Electrical Safety

| Standard (Edition) | Standard title |
|---|---|

| | |
|---|---|
| IEC 60601-1 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. |
| IEC 60601-1-2 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic compatibility - Requirements and tests |
| IEC 60601-1-6 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |
| IEC 60601-2-2 | Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories |
| IEC 62366-1 | Medical devices — Part 1: Application of usability engineering to medical devices |

5.6.2. Software Validation

The 10THERMA is a medical device whose level of concern for software is classified as 'Moderate'. The software verification and validation report are provided.

| Standard (Edition) | Standard title |
|---|---|
| IEC 62304 | Medical device software. Software life-cycle processes |

5.6.3. Biocompatibility

| Standard (Edition) | Standard title |
|---|---|
| ISO 10993-1 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| ISO 10993-5 | Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity |
| ISO 10993-10 | Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization |
| ISO 10993-23 | Biological evaluation of medical devices - Part 23: Tests tor irritation |

5.6.4. Risk Analysis

| Standard (Edition) | Standard title |
|---|---|
| ISO 14971 | Medical devices -Application of risk management to medical devices. |

**5.7 Substantial Equivalence**

The proposed device uses similar or identical technology as the predicate devices and has same intended uses. Based upon the predicted overall performance characteristics for 10THERMA, Tentech Inc. believes that no significant differences in usage of its underlying technological principles between 10THERMA and the predicate device.

## 5.8 Conclusions

On the basis of the information provided in this Summary, Tentech Inc. believes that 10THERMA is substantially equivalent to legally commercialized predicate devices for the purposes of this 510 (k) submission.