November 17, 2025

Starmed Co., Ltd.
% Do Hyun Kim
CEO
BT Solutions, Inc.
Unit 303, Gonghang-daero 337, Gangseo-gu
Seoul, Seoul 07590
Korea, South

Re: K251566
Trade/Device Name: TS-RF Generator (STS10)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 15, 2025
Received: October 15, 2025

Dear Do Hyun 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.11.17 20:30:37 -05'00'

Colin Kejing Chen
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251566

Please provide the device trade name(s).

TS-RF Generator (STS10)

Please provide your Indications for Use below.

The TS-RF Generator is indicated for use in general surgical procedures to cut and coagulate soft tissue.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

TS-RF Generator

510(k) Summary

1. Administrative Information

1.1. Sponsor

Manufacturer	STARMED CO., LTD. B-Dong, 4F&12F, 158, Haneulmaeul-ro. Ilsandong-Gu, Goyang-Si Gyeonggi, Republic of Korea
Contact Person	Honggeun Lee/PRRC & QMR Tel) +82-31-816-3546(209) Fax) +82-31-816-4546 Email) lhg1186@STARmed4u.com
Preparation Date	May 22, 2025

1.2. Consultant

Company	BT Solutions, Inc. Unit 303, Gonghang-daero 337, Gangseo-gu, Seoul, 07590, Republic of Korea
Contact Person	Do Hyun Kim, CEO Tel) +82 2-538-9140 Fax) +82 2-538-9140 Email) ceo@btsolutions.co.kr

2. Device information

○ Trade Name:	TS-RF Generator
○ Common Name:	Electrosurgical System
○ Regulation Number:	21 CFR 878.4400
○ Regulation Name:	Electrosurgical, Cutting & Coagulation & Accessories
○ Regulation Class:	Class II
○ Product Code:	GEI
○ Review Panel:	General & Plastic Surgery

3. Predicate device information

○ Predicate Device: K122278(Baylis Medical Company Radiofrequency Perforation Generator, Model RFP-100A and optional footswitch(Model:RFA-FS))

4. Description of the device

The TS-RF Generator consists of an RF generator, cables, and components. This TS-RF Generator is indicated for use in general surgical procedures to cut and coagulate soft tissue. Radiofrequency power is supplied and controlled with a maximum of 50 watts. Data Logs can be stored by connecting the USB Flash Driver with the communication terminal of the rear panel of the RF generator.

5. Indication for use

The TS-RF Generator is indicated for use in general surgical procedures to cut and coagulate soft tissue.

6. Technological characteristics

Comparison Item	Subject Device	Predicate Device
510(k) Number	-	K122278
Proprietary Name	TS-RF Generator	Baylis Medical Company Radiofrequency Perforation Generator, Model RFP-100A and optional footswitch(Model:RFA-FS)
Model Number	STS10	Model RFP-100A
Manufacturer	STARmed Co., Ltd.	Baylis Medical Company Inc.
Regulatory Class	Class II	Class II
Regulation Number	21 CFR 878.4400	21 CFR 878.4400
Product Code	GEI	GEI
Indication for Use	The TS-RF Generator is indicated for use in general surgical procedures to cut and coagulate soft tissue.	The BMC Radiofrequency Perforation Generator is indicated for us in general surgical procedures to cut and coagulate soft tissue.
Prescription or OTC	Prescription	Prescription
Monopolar or Bipolar	Monopolar	Monopolar
Size and weight	330 x 402.5 x 160.8(mm) 6.6 kg	285 x 396 x 178(mm) 9.1kg
Voltage range:	100-240V~	100-240V~
Output Power:	50W (300 ohm is the rated “nominal’ load)	50W (*Into resistive load range of 100-6000 ohms 300 ohm is the rated “nominal” load)
Frequency:	468 kHz ± 5 %, Sinusoidal	468 kHz, Sinusoidal
Output impedance	100-6000 ohm	100-6000 ohm

The predicate device and the TS-RF Generator have similar design characteristics and technical specifications. The difference between the two devices is size and weight.

7. Summary of non-clinical data

Non-clinical tests were conducted to verify that the subject device met all design specifications as was substantially equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- Electromagnetic Compatibility and Electrical Safety

  The Subject device is an active device and complies with the following general and particular standards.

  - IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
  - IEC 60601-1-2:2014+A1:2020 CSV, EN 60601-1-2:2015/A1:2021
  - IEC 60601-1-6:2010+A1:2013+A2:2020
  - IEC 60601-2-2:2017+A1:2023

- Performance Testing - Bench

In order to verify the design characteristics of the subject device as specified in the comparison table, bench testing was performed in accordance with the FDA guidance "*Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery*" including the test items below.

- Thermal Effects on Tissue

A comparative evaluation of the thermal effect area of the TS-RF Generator and the predicate device was performed. As a result of the test, the devices had similar perforation outer diameter and there was no significant difference.

8. Summary of clinical data

We do believe that no clinical evidence is required to show substantial equivalence to the predicate device.

9. Conclusion

A comparison of the technical characteristics of the TS-RF Generator and the Predicate Device shows that they are very similar in design characteristics and technical specifications. Non-clinical tests per FDA recognized international standards and the FDA guidance on Electrosurgical Devices for General Surgery, support that the target device conforms to the recognized standard and is substantially equivalent to the predicate device for the intended use.

Therefore, TS-RF Generator have been demonstrated to be equivalent to predicate devices.