April 29, 2024

Classys Inc.
James Hoon Lim
Regulatory Affairs Team Manager, Classys Inc.
208 Teheran-ro, Gangnam-gu
Seoul, 06220
Korea, South

Re: K240248
Trade/Device Name: Volnewmer™
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 30, 2024
Received: January 30, 2024

Dear James Hoon Lim:

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: 2024.04.29 09:23:20 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

Volnewmer™

Indications for Use *(Describe)*

Volnewmer™ is intended for use in dermatologic procedures for electrocoagulation and hemostasis of soft tissue.

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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The assigned 510(k) Number: K240248

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

- Name: CLASSYS Inc.
- Address: 208 Teheran-ro, Gangnam-gu, Seoul, Republic of Korea
- Postal Code: 06220
- General Telephone: +82-2-1544-3481

Contact Person:

- Contact Person: Mr. James Hoon Lim (RA Team Manager, Classys)
- Tel: +82-10-3351-1414
- Email: h.lim@classys.com

2. Date of the summary prepared: April 25, 2024

3. Subject Device Information

- Type of 510(k): Traditional
- Trade Name: Volnewmer™
- Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories
- Common Name: Radio Frequency Therapy System
- Review Panel: General & Plastic Surgery
- Product Code: GEI
- Regulation: 21 CFR 878.4400
- Regulatory Class: Class II

4. Predicate Device Information

- 510(k) Number: K170758
- Trade/Device Name: Thermage FLX System
- Regulation Number: 21 CFR 878.4400
- Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
- Regulatory Class: Class II
- Product Code: GEI, ISA
- Manufacturer: Solta Medical, Inc.

5. Reference Device Information

- 510(k) Number: K211562
- Trade/Device Name: Virtue RF
- Regulation Number: 21 CFR 878.4400
- Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
- Regulatory Class: Class II
- Product Code: GEI
- Manufacturer: ShenB Co., Ltd.

6. Device Description

Volnewmer™ is a noninvasive monopolar radiofrequency (RF) therapy system. The radiofrequency output of the device is 6.78 MHz, and the maximum output power is 115 W.

- Volnewmer™ delivers radiofrequency energy for selective coagulation of tissue while conductively cooling the epidermis.
- Volnewmer™ delivers energy from the disposable/reusable tip to the patient.
- Volnewmer™ employs radiofrequency tuning to provide radiofrequency energy across a range of impedances for delivery to the patient through the disposable/reusable tip.

Volnewmer™ consists of the following components:

- Console
- Handpiece x2
- Treatment Tips
- Accessories:
  - Return Pad
  - Return Pad Cable
  - Coupling Gel
  - Footswitch

7. Indications for Use

Volnewmer™ is intended for use in dermatologic procedures for electrocoagulation and hemostasis of soft tissue.

8. Comparison to Predicate Device

The differences between the subject device and predicate device do not raise new issues of safety or effectiveness.

Comparison Item	Proposed Device, Volnewmer™	Predicate Device, Thermage FLX System,	Reference Device, Virtue RF
510(k) Number	K240248	K170758	K211562
Trade/Device Name	Volnewmer™	Thermage FLX System	Virtue RF
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400
Regulation Name	Electrosurgical Cutting and Coagulation Device and Accessories	Electrosurgical Cutting and Coagulation Device and Accessories	Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class	Class II	Class II	Class II
Product Code	GEI	GEI, ISA	GEI
Manufacturer	CLASSYS INC., Inc.	Solta Medical, Inc.	ShenB Co., Ltd.
Indication For Use / Intended Use	Dermatologic procedures for electrocoagulation and hemostasis of soft tissue.	Dermatologic and general surgical procedures for electrocoagulation and hemostasis of soft tissue.	The Virtue RF System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
Output Frequency	6.78MHz	6.78MHz	0.5 MHz ~ 2 MHz
Max Output Power	115 W	400 W	220 W
User Interface	LCD Touchscreen Technology for user interaction and controls.	LCD Touchscreen Technology for user interaction and controls.	LCD Touchscreen Technology for user interaction and controls.
Tip Specification	• 0.25 cm^2 • 3 cm^2 • 4 cm^2 • 16 cm^2	• 0.25 cm^2 • 3 cm^2 • 4 cm^2 • 16 cm^2	• 2.78 cm^2 / 36pin • 3.12 cm^2 / 12pin • 6 cm^2 / 36pin
Cooling Mechanism	Water cooling system	R-134A Cryogen Gas Cooling	Water cooling system

9. Summary of Non-Clinical Testing

Verification/validation activities from non-clinical testing as described below demonstrate that the differences do not raise any new issues of safety or effectiveness of the subject device compared to the predicate device.

EMC and Electrical safety of the subject device was tested in compliance with IEC 60601-1 Edition 3.2; IEC 60601-1-2 Edition 4.0 and IEC 60601-2-2 Edition 6.0

Thermal Effect & Safety In-Vivo Test were conducted for evaluating the safety and performance profile of the subject device. The test results support the substantial equivalence.

Bench testing was performed to ensure that the subject device performs as intended and meets design specifications.

Biocompatibility testing was performed in compliance with ISO 10993-1 and FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (issued on September 8, 2023) to demonstrate biocompatibility of the patient-contacting components of the device.

Software Verification and Validation testing were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions" (issued on June 14, 2023). The software documentation level for the subject device is considered as 'Enhanced Documentation'.

11. Conclusion

The Volnewmer™ shares the same indications for use, fundamental scientific technology, design and functional features. Non-clinical test results demonstrate that the Volnewmer™ safety and performance are substantially equivalent to the predicate device for the requested indications for use.