July 13, 2026

Classys, Inc.
Gene Choi
Regulatory Affairs Team Manager, CLASSYS Inc.
208, Teheran-Ro, Gangnam-Gu
Seoul, 06220
Republic Of Korea

Re: K253504
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: June 12, 2026
Received: June 12, 2026

Dear Gene Choi:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

JAMES H. JANG -S

Digitally signed by JAMES H. JANG -S
Date: 2026.07.13 13:57:43 -04'00'

For
Colin K. Chen, 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

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.	K253504

Please provide the device trade name(s).

Volnewmer™

Please provide your Indications for Use below.

Volnewmer™ is intended for use in dermatologic procedures for electrocoagulation and hemostasis of 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)

The assigned 510(k) Number: K253504

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: Gene Choi (RA Team Manager, Classys)
- Tel: +82-10-3351-1414
- Email: h.lim@classys.com

2. Date of the summary prepared: July 10, 2026

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: 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
- Manufacturer: CLASSYS Inc.

5. Reference Device Information

- 510(k) Number: K240897
- Trade/Device Name: CELLINEW
- Regulation Number: 21 CFR 878.4400
- Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
- Regulatory Class: Class II
- Product Code: GEI
- Manufacturer: Viol 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 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 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 proposed device Volnewmer™ is identical to the predicate device Volnewmer™ (K240248) in terms of intended use, technological characteristics, hardware configuration, energy output, treatment parameters, and overall design. The only modification is the addition of a software-controlled Repeat Mode, which enables automated, continuous delivery of shots for user-convenience.

Comparison Item	Proposed Device, Volnewmer™	Predicate Device, Volnewmer™, K240248	Reference Device, CELLINEW, K240897	Assessment of Substantial Equivalence
510(k) Number	K253504	K240248	K240897	N/A
Trade/Device Name	Volnewmer™	Volnewmer™	CELLINEW	N/A
Regulation No.	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	Identical
Regulation Name	Electrosurgical Cutting and Coagulation Device and Accessories	Electrosurgical Cutting and Coagulation Device and Accessories	Electrosurgical Cutting and Coagulation Device and Accessories	Identical
Regulatory Class	Class II	Class II	Class II	Identical
Product Code	GEI	GEI	GEI	Identical
Manufacturer	CLASSYS Inc.	CLASSYS Inc.	Viol Co., Ltd.	N/A
Indication For Use / Intended Use	Dermatologic procedures for electrocoagulation and hemostasis of soft tissue.	Dermatologic procedures for electrocoagulation and hemostasis of soft tissue.	Dermatologic and general surgical procedures for electrocoagulation and hemostasis.	Identical to K240248
Output Frequency	6.78MHz	6.78MHz	6.78MHz	Identical
Max Output Power	115 W	115 W	400W	Identical to K240248
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.	Identical
Tip Specification	• 0.25 cm^2 • 3 cm^2 • 4 cm^2	• 0.25 cm^2 • 3 cm^2 • 4 cm^2	• 0.25 cm^2 • 4 cm^2	Identical to K240248

Comparison Item	Proposed Device, Volnewmer™	Predicate Device, Volnewmer™, K240248	Reference Device, CELLINEW, K240897	Assessment of Substantial Equivalence
	• 16 cm^2	• 16 cm^2		
Cooling Mechanism	Water cooling system	Water cooling system	Cryogen	Identical to K240248

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'.

Cybersecurity testing was conducted, and documentation was provided as recommended by FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (issued on June 27, 2025).

10. Final Conclusion

The Volnewmer™ shares the same indications for use, fundamental scientific technology, design and functional features as the predicate device. The reference device is used to support the subject device repeated use technological characteristic. Performance testing results demonstrate that the Volnewmer™ safety and performance are substantially equivalent to and as safe and effective as the predicate device as indicated for use.