January 03, 2025

Eunsung Global Corp.
℅ Milly
RA Consultant
Kmc, Inc.
(G-Plus Tower, #1709) 123, Digital-ro 26-gil, Guro-gu
Seoul, 08390
Korea, South

Re: K233118
Trade/Device Name: DUET-V (Model: ESK-3261DV)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 28, 2024
Received: December 3, 2024

Dear Milly:

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,

James H. Jang -S

Digitally signed by James H. Jang -S
Date: 2025.01.03 12:29:16 -05'00'

For
Long 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

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)*
K233118

Device Name
DUET-V (Model: ESK-3261DV)

Indications for Use *(Describe)*
The radiofrequency energy delivery components of the DUET-V(ESK-3261DV) and Accessories are indicated for use in:
- Fractional Tips (FRF Tips): Fractional Tip is intended for use in dermatological procedures requiring ablation and resurfacing of the skin.
- Thermal Tips (TRF Tips): Dermatologic and general surgical procedures for electrocoagulation

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
(K233118)

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: January 2, 2025

1. **Applicant / Submitter**

EUNSUNG GLOBAL CORP

120, Gieopdosi-Ro, Jijeong-Myeon, Wonju-Si, Gangwon-do, 26354, Republic of Korea

Tel : +82-33-760-1771 Email : juanms@esglobal.co.kr

2. **Official Correspondent (RA Consultant)**

Milly (RA Consultant / KMC, Inc.)

Address: (G-Plus Tower, # 1709) 123, Digital-ro 26-gil, Guro-gu, Seoul, 08390, South Korea

Tel: +82-70-8965-5554 Email: milly@kmcerti.com

3. **Device Information**

3.1. Trade Name: DUET-V (Model: ESK-3261DV)

3.2. Model Name: ESK-3261DV

3.3. Classification Name:

21 CFR 878.4400 Electrosurgical cutting and coagulation device and accessories

3.4. Product Code: GEI

3.5. Device Class: 2

4. **Predicate Device**

Predicate Device 1 for Thermal RF Tip

4.1. K-Number: K173759

4.2. Manufacturer: Solta Medical Inc.

4.3. Model Name: Thermage CPT System and Accessories

Predicate Device 2 for Fractional RF Tip

4.4. K-Number: K201164

4.5. Manufacturer: Venus Concept USA Inc.

4.6. Model Name: Venus Viva MD Device

5. General Description

DUET-V (Model: ESK-3261DV) is a High Frequency Therapy Device system using 4 MHz high frequency electrical current.

Single-use, disposable Treatment Tips attach to the handpiece that comes into contact with the patient during treatment procedures. Treatment tips are classified as direct skin contact devices of limited duration (<24 hours). The RF handpiece has 2 types of fractional tips and 3 types of thermal tips. The tips are disposable and are provided in a non-sterile state.

Mono-polar electrodes TRF TIP-S, TRF TIP-R, and TRF TIP-E are used with a grounding pad. Bipolar electrodes FRF TIP-64 and FRF TIP-100, unlike mono-polar electrodes, do not have a ground pad and current flows between electrodes on the contact surface.

The tip has three modes: Shot mode, Auto Shot mode, and Continuous mode

- Shot Mode – this mode delivers the output value set by the user once
- Auto Shot Mode – In this mode, the set output value delivered continuously according to the interval time set by the user. (only TRF-TIP-S)
- Continuous Mode – this mode continuously delivers RF current until stopped by the user.

6. Indication for use

The radiofrequency energy delivery components of the DUET-V(Model: ESK-3261DV) and Accessories are indicated for use in:

- Fractional Tips (FRF Tips): Fractional Tip is intended for use in dermatological procedures requiring ablation and resurfacing of the skin.
- Thermal Tips (TRF Tips): Dermatologic and general surgical procedures for electrocoagulation

7. Comparison of the subject device to the predicate device

The following comparison table is presented to demonstrate substantial equivalence.

7.1 RF Device Including Non-fractional RF Tip (TRF Tip)

Descriptive Information		Subject Device	Predicate Device 1
Manufacturer		EUNSUNG GLOBAL CORP	Solta Medical Inc.
Regulation number		21 CFR 878.4400	21 CFR 878.4400
Regulation Name		Electrosurgical Cutting and Coagulation Device and Accessories	Electrosurgical Cutting and Coagulation Device and Accessories
Trade Name		DUET-V (Model: ESK-3261DV)	Thermage CPT System and Accessories
510(k) number		-	K132431 K173759
Regulatory Number and Classification Product Code		GEI	GEI, ISA
Indications for Use		The radiofrequency energy delivery components of the DUET-V(ESK- 3261DV) and Accessories are indicated for use in: • Thermal Tips (TRF Tips): Dermatologic and general surgical procedures for electrocoagulation	The radiofrequency energy delivery components of the Thermage CPT System and Accessories are indicated for use in: • Dermatologic and general surgical procedures for electrocoagulation and hemostasis; • Non-invasive treatment of periorbital wrinkles and rhytids including upper and lower eyelids; • Non-invasive treatment of wrinkles and rhytids.
Prescription or OTC		Prescription use	Prescription use
ESU	Energy	RF	RF
	Treatment type	Non-Ablative	Non-Ablative
	Input power	110-240VAC, 50/60Hz	Unknown
	Maximum power	250VA	500W
	Operating frequency	4MHz	6.78MHz
	Treatment level	Multiple treatment level	Multiple treatment level
	Mode of Operation	Manual or Footswitch	Manual or Footswitch
	Characteristic	Hand-held	Hand-held
	Electrode	Removable exchangeable to different	Removable exchangeable to different

Descriptive Information		**Subject Device**	**Predicate Device 1**
Hand-piece		size	size
	Condition of use	Disposable Single patient use only	Disposable Single patient use only
	Electrode type	Mono-polar	Mono-polar
Active accessory	Electrode type	Mono-polar	Mono-polar
	Dimension	TRF TIP-S: 37(L) x 36.1(D) x 27.7 (H) mm / 13 g TRF TIP-E: 37.5(L) x 36.1(D) x 37.1(H) mm / 10 g TRF TIP-R: 37.5(L) x 36.1(D) x 28.4 (H) mm, 12 g	Unknown
	Treatment area	TRF TIP-S / 20.8 x 20.8 mm TRF TIP-E / 9.80mm⌀ TRF TIP-R / 18.60mm⌀	0.25cm^2 ~ 16cm^2
	Rated voltage	TRF TIP-S / 317 Vp TRF TIP-E / 238 Vp TRF TIP-R / 290 Vp	Unknown
Neutral electrode	Neutral pad was registered with K073360 and attached the certification of the product in Appendix 16.		

7.2 RF Device Including Fractional RF Tip (FRF Tip)

Descriptive Information		Subject Device	Predicate Device 2
Manufacturer		EUNSUNG GLOBAL CORP	Venus Concept USA Inc
Regulation number		21 CFR 878.4400	21 CFR 878.4400
Regulation Name		Electrosurgical Cutting and Coagulation Device and Accessories	Electrosurgical Cutting and Coagulation Device and Accessories
Trade Name		DUET-V (Model: ESK-3261DV)	Venus Viva MD™
510(k) number		-	K201164
Regulatory Number and Classification Product Code		GEI	GEI
Indications for Use		The radiofrequency energy delivery components of the DUET-V(ESK-3261DV) and Accessories are indicated for use in: • Fractional Tips (FRF Tips): Fractional Tip is intended for use in dermatological procedures requiring ablation and resurfacing of the skin.	The Venus Viva MD™ is a non-invasive device intended to be used by aesthetic-related physicians or dermatologists. • When used with the Viva MD applicator, the Venus Viva MD™ device is intended for use in dermatological procedures requiring ablation and resurfacing of the skin. • When used with the Diamondpolar applicator, the Venus Viva MD™ device is intended for use in dermatological and surgical procedures for females for the non- invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin type I-IV.
Prescription or OTC		Prescription use	Prescription use
ESU	Energy	RF	RF
	Treatment type	Ablative	Ablative
	Input power	110-240VAC, 50/60Hz	110-240VAC, 50/60Hz
	Maximum power	250VA	120W
	Operating frequency	4MHz	1MHz, 0.46MHz
	Treatment level	Multiple treatment level	Multiple treatment level
	Mode of Operation	Manual or Footswitch	Manual or Footswitch
Hand-piece	Characteristic	Hand-held	Hand-held
	Electrode	Removable exchangeable to different size	Removable exchangeable to different size
	Treatment tip	Sterile	Sterile
	Condition of	Disposable Single patient use only	Disposable Single patient use only

Descriptive Information		Subject Device	Predicate Device 2
	use		
	Electrode type	Bi-polar	Bi-polar
Active accessory	Electrode type	Bi-polar	Bi-polar
	Dimension	FRF TIP-64: 37(L) x 36.1(D) x 27.7 (H) mm / 13 g FRF TIP-100: 37(L) x 36.1(D) x 27.7 (H) mm / 13 g	80 pin tip: 1.33cm^2 160 Pin tip: 1.33cm^2
	Treatment area	FRF TIP-64 / 20.8 x 20.8 mm FRF TIP-100 / 20.8 x 20.8 mm	Unknown
	Max Output Power	FRF Tip-64: 0.12J FRF TIP-100: 0.19J	2mJ/pin

8. Description of Performance Testing

8.1. Biocompatibility

Biocompatibility tests were conducted to ensure that no risks arise from biological hazards associated with materials of manufacture and the final device.

1) ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2) ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
3) ISO 10993-10:2020, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
4) ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation
5) ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

8.2. Software

The firmware is intended to control the device. It is installed in a microprocessor of the device. The firmware was verified and validated according to FDA Guidance "Content of Premarket Submission for Software Contained in Medical Devices" and IEC 62304: 2006 + A1:2015, Medical device software - Software life cycle processes.

Cybersecurity of the subject device is compliance to FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"

8.3. Electrical Safety and Electromagnetic compatibility

Electrical hazard and high temperature hazard are included within the device. The risks are controlled by design, protection method and information according to the FDA recognized standard, AAMI/ANSI ES 60601-1: 2005+A1: 2012.

Electromagnetic compatibility was tested and verified according to the FDA recognized

standard, IEC 60601-1-2:2020

8.4. **Reprocessing**

Re-usable part of the subject device is intended to be cleaned and disinfected by user after use. Therefore, the cleaning and disinfection is established and validated in accordance with FDA 'Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling'

8.5. **Performance Testing – Bench**

8.5.1.General

Item	Criteria
Frequency Test	Not exceed the standard value of 4MHz
Output waveform	Confirm the waveform shape as sine wave
Power variation characteristic	1) Input voltage fluctuates within the range of within the range of ±10% of 220V, 2) No abnormalities in each part
Output voltage and current	Be within must be within ±20% of standard value
Output ON/OFF time	Be within must be within ±10% of standard value
Max. output voltage and current	Be within must be within ±20% of standard value when voltage connect a 500Ω load to the output terminal, set the maximum output
Accuracy of temperature control	Be within ± ± 1℃ of set value
Automatic Stop function when temperature rise	Automatically stop at the set temperature
Switch interlock	Be normally operated of switch interlock when control the foot or hand-piece switch select.
Output function upon skin contact	Output comes out when two or more of the four skin contact of FRF tip

8.5.2.Neutral electrode

The neutral electrode was supplied by sub-contracted company as finished product and already clearance (K073360, Trade Name: Proplate) product of neutral electrode.

8.5.3.System testing

1) Thermal Effects on Tissue

The subject device's function and electrical specifications are the same as the predicate device. Thermal Effects on Tissue test was performed by FDA guidance 'Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery' requirements.

2) Temperature Monitoring

The subject device was performed about temperature during operation.
The temperature monitoring was performed by FDA guidance 'Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery' requirements

3) Accuracy of output

ESU power output accuracy Performance test (according to test as IEC 60601-2-2 201.12.1.101) has been conducted

Applied Clause	Criteria
201.12.1.101a	Accuracy of Output control setting _ monopolar Acceptance criteria ±20%
201.12.1.101b	Accuracy of Output control setting _ bipolar Acceptance criteria ±20%
201.12.1.102a	Monotonicity of Output control setting _ monopolar Acceptance criteria ±20%
201.12.1.102b	Monotonicity of Output control setting _ bipolar Acceptance criteria ±20%

9. Conclusion

The subject device has similar design (functions, components, accessories, and shape) to the predicate device 1 (K173759) and predicate device 2 (K201164). The performance testing has been conducted according to the FDA recognized standards and the results demonstrate substantially equivalent performance to compare to the predicate devices.
Therefore, subject device is substantially equivalent to the predicate devices for requested indications for use.