December 20, 2024

SKINGRAB Co., Ltd.
Mr. Oskar Lee
CEO
1306-1307, KM TOWER, 95, Gasan digital 2-ro, Geumcheon-gu
Seoul,
Korea, South

Re: K242688
Trade/Device Name: Finiff System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 26, 2024
Received: November 26, 2024

Dear Mr. Oskar Lee:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.12.20 11:47:52 -05'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242688

Device Name

Finiff System

Indications for Use *(Describe)*

The Finiff System is intended for use in Dermatologic and General Surgery procedures that require electrocoagulation and hemostatis.

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.

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510(k) #: K242688

510(k) Summary

Prepared on: 2024-11-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	SKINGRAB Co., Ltd.
Applicant Address	1306-1307, KM TOWER, 95, Gasan digital 2-ro, Geumcheon-gu Seoul Korea, South
Applicant Contact Telephone	070-7954-1388
Applicant Contact	Mr. Oskar Lee
Applicant Contact Email	ceo@skingrab.co.kr

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Finiff System
Common Name	RF Generator
Classification Name	Electrosurgical Device
Regulation Number	21 CFR 878.4400
Product Code(s)	GEI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201685	Potenza	GEI
K170758	Thermage FLX System	GEI

Device Description Summary

21 CFR 807.92(a)(4)

The Finiff System is a High Frequency Electrosurgical Unit that uses electrical currents to coagulate tissue. The Finiff System consists of a console that houses an RF generator as well as the electronics. The user interface is a touchscreen that is located on the console. There are two handpieces that attach to the console:

• The VertoRF Handpiece is a microneedling handpiece that delivers energy in 2 frequencies: 1mHz and 2mHz. The VertoRF has one disposable tip configuration that consists of 25 needles and penetrates the tissue up to 4mm in depth.

• Ther VitaRF Handpiece delivers noninvasive RF energy at a frequency of 6.78 MHz. The VitaRF handpiece has 2 Treatment Tips: the VitaRF F-Tip and the VitaRF E-Tip

In addition to the console and the 2 handpieces, there are accessories as follows:
• Power Cord
• Footswitch (optional)
• Cryogen canister
• Return Pad
• Coupling fluid

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Finiff System is intended for use in Dermatologic and General Surgery procedures that require electrocoagulation and hemostatis.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use are the same.

Technological Comparison

21 CFR 807.92(a)(6)

The FINIFF shares the same indications for use, mode of operation, and overall design as the predicate device. The differences between the systems are small and do not have any impact on safety or efficacy. The predicate device has three sizes of electrodes whereas the FINIFF has two. The predicate functions in both monopolar and bipolar modes while the FINIFF has only a monopolar function. There are slight differences in the RF duration but they are not large enough to impact the performance of the device. The FINIFF and the predicate device can therefore be considered substantially equivalents.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Bench Testing and histology testing was conducted to show the performance of the Finiff System and its applicators. There are no new concerns for safety or efficacy raised. Therefore, the Finiff System is substantially equivalent to the predicate device.