September 29, 2025

Hironic Co., Ltd.
Lee Gwijin
Official Correspondent
19F, U-TOWER, 767, Sinsu-ro, Suji-gu
Yongin-si, Gyeonggi-do 16827
Korea, South

Re: K251334
Trade/Device Name: New Doublo 2.0
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 30, 2025
Received: April 30, 2025

Dear Lee Gwijin:

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: 2025.09.29 20:37:53 -04'00'

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.	K251334

Please provide the device trade name(s).

NEW DOUBLO 2.0

Please provide your Indications for Use below.

The NEW DOUBLO 2.0 with RM and RM(B) handpiece is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.
The NEW DOUBLO 2.0 with PS handpiece is intended for the removal and destruction of skin lesions and coagulation of 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)

HIRONIC

510(k) Summary

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

807.92(a)(1) – Submitter Information	
Applicant	Hironic Co., Ltd.
Address	19F, U-TOWER, 767, Sinsu-ro, Suji-gu, Yongin-si, Gyeonggi-do, 16827, Republic of Korea
Phone Number	+82-31-525-7000
Contact Person	Gwijin Lee
Contact Information	19F, U-TOWER, 767, Sinsu-ro, Suji-gu, Yongin-si, Gyeonggi-do, 16827, Republic of Korea t. +82-31-525-7000, e. ra@hironic.com
Date Prepared	24 September 2025

807.92(a)(2) – Device Name and Code	
Trade/Device Name	NEW DOUBLO 2.0
Common Name	Electrosurgical System
Classification Name	Electrosurgical cutting and coagulation device and accessories
Product Code	GEI
Regulation Number	21 CFR 878.4400
Regulatory Class	II
Review Panel	General & Plastic Surgery (ODE)

807.92(a)(3) – Legally marketed device(s) to which equivalence is claimed	
Primary Predicate Device	K233123 SILKRO
Predicate/Reference Device	K241099 PLASONIC

807.92(a)(4) – Device Description
This device is an instrument used for tissue coagulation by means of high-frequency current. It consists of the main unit, three handpieces, foot switch, LCD touchscreen and power cable. The NEW DOUBLO 2.0 has three handpieces: The device is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis with RM and RM(B) handpieces and the removal and destruction of skin lesions and coagulation of tissue with PS handpiece. The device is intended for use by trained healthcare professionals in a clinical setting to provide controlled radiofrequency therapy through non-invasive procedure. RF uses electromagnetic wave frequencies to generate an electric field within tissue to cause heating. The amount of energy delivered to tissue is proportional to the current, time, and resistance within the tissue, also known as impedance. Tissue impedance is the main variable in the amount of heat delivered by the generated electric current.

High frequency amplification is performed and it is transmitted to the handpiece. The corresponding output is controlled through the Foot Switch and Hand Switches, and when the Foot Switch and Hand Switches are pressed, each handpiece irradiates the transmitted high-frequency energy to the skin.

807.92(a)(5) – Indication for Use

The NEW DOUBLO 2.0 with RM and RM(B) handpiece is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.
The NEW DOUBLO 2.0 with PS handpiece is intended for the removal and destruction of skin lesions and coagulation of tissue.

807.92(a)(6) – Summary of the Technological Characteristics of the Device Compared to the Predicate

1. Primary Predicate Device

	Proposed Device	Primary predicate Device	Comparison Comment
510(k) Number	K251334	K233123	
Manufacturer	Hironic Co., Ltd.	Hironic Co., Ltd.	
Trade/Device Name	NEW DOUBLO 2.0	SILKRO	
Classification Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	
Indication for use	Intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.	Intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.	Identical
Output energy type	Radio Frequency	Radio Frequency	Identical
User interface	Color Touch Panel	Color Touch Panel	Identical
Operating Frequency	0.5, 1, 2 ㎒	2 ㎒	Similar
Rated Input	100 – 240 VAC, 50/60 ㎐	100 – 240 VAC, 50/60 ㎐	Identical
Max. Power	RM, RM(B) Handpiece: 19.88 W ± 20%	RM Handpiece: 20.520 W ± 20%	Similar
RF Duration	RM, RM(B) Handpiece: 50 – 950 ㎳	RM Handpiece: 50 – 950 ㎳	Identical
Needle Insert Depth	RM, RM(B) Handpiece: 0.5 – 3.5 ㎜	RM Handpiece: 0.5 – 3.5 ㎜	Identical
Repetition	RM, RM(B) Handpiece: 0.2 – 0.8, 1.0, 2.0 sec, Single	RM Handpiece: 0.2, 0.5, 0.8, 1.0, 2.0 sec, Single	Similar
Mode of Operation	RM/RM(B) Handpiece: Bipolar Type	RM Handpiece: Bipolar Type	Identical

Electrode(Needle) Type	RF Micro Needle Tip for RM, RM(B) Handpiece: 25 pin, 49 pin	RF Micro Needle Tip for RM Handpiece: 25 pin, 49 pin	Identical
Single Use	RF Micro Needle Tip for RM, RM(B) Handpiece	RF Micro Needle Tip for RM Handpiece	Identical
Sterilization	EO Gas	EO Gas	Identical

2. Predicate/Reference Device

	Proposed Device	Predicate/Reference Device	Comparison Comment
510(k) Number	K251334	K241099	
Manufacturer	Hironic Co., Ltd.	Hironic Co., Ltd.	
Trade/Device Name	NEW DOUBLO 2.0	PLASONIC	
Classification Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	
Indication for use	Used in the removal and destruction of skin lesions and coagulation of tissue.	Used in the removal and destruction of skin lesions and coagulation of tissue.	Identical
Mode of Operation	Radio Frequency (Plasma)	Radio Frequency (Plasma)	Identical
Output	Monopolar	Monopolar	Identical
Power Supply	100 – 240 VAC, 50/60 Hz	100 – 240 VAC, 50/60 Hz	Identical
Frequency	41 kHz	41 kHz	Identical

807.92(b)(1) – Non-clinical tests submitted

- IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-2:2017, IEC 60601-2-2:2017/AMD1:2023 Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6:2010, AMD1:2013, AMD2:2020 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 62304:2006 Medical device software – Software life cycle processes is evaluated according to the FDA-recognized consensus standard
- IEC 62366-1:2015 Medical device – Part 1: Application of usability engineering to medical devices is evaluated in accordance with the FDA-recognized consensus standard
- ISO 14971:2019 Medical devices – Application of risk management to medical devices

- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- In the ex vivo model, the handpieces were applied in the same way as applied to the actual human body and the temperature change of the application site was analyzed through a thermal imaging camera. In addition, the length, width and depth of tissue coagulation at the application site were analyzed through photography and histological evaluation.

807.92(b)(2) – Clinical tests submitted
No clinical test was performed.

Conclusions drawn from clinical and non-clinical tests submitted
The NEW DOUBLO 2.0 is substantially equivalent to its primary predicate device and predicate/reference device with same indication for use and technological characteristics. The non-clinical data for proposed device, including biocompatibility, bench testing, hardware and software documentation shows that the device should perform as intended in the specified use. In addition, the Electromagnetic Compatibility and Electrical Safety test shows that the device is safe to use and meets required standards. In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification that we conclude that substantially equivalent with predicate device.