November 8, 2024

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

Re: K241099
Trade/Device Name: Plasonic (Plasonic)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, IMI
Dated: October 11, 2024
Received: October 11, 2024

Dear Gwijin 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: 2024.11.08 07:34:22 -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)*

K241099

Device Name

PLASONIC (PLASONIC)

Indications for Use *(Describe)*

The PLASONIC with PLAPASS handpiece (Radiofrequency) is intended for the removal and destruction of skin lesions and coagulation of tissue.

The PLASOINC with SONOPASS handpiece (Ultrasound) is intended for pain relief, reduction of muscle spasms, localized increase in blood flow, increase range of motion of contracted jointed using heat and stretch techniques.

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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HIRONIC

510(k) Summary

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

1. Submitter Information - 807.92(a)(1)

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
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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, m. +82-10-5049-2959, e. ra@hironic.com
Preparation Date	Oct. 11th, 2024

Date 510(k) summary prepared: Oct. 11th, 2024

2. Device Name and Code - 807.92(a)(2)

Trade/Device Name	PLASONIC
Common Name	Electrosurgical System
Classification Name	Electrosurgical cutting and coagulation device and accessories
Product Code	GEI, IMI
Regulation Number	21 CFR 878.4400
Regulatory Class	II
Review Panel	General & Plastic Surgery (ODE)

3. Legally marketed device(s) to which equivalence is claimed - 807.92(a)(3)

Predicate Device – 1	K223222 Applicant: Neauvia North America, Inc Trade/Device Name: Plasma IQ Regulation Number: 21 CFR 878.4400 Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories Regulatory Class: Class II Product Code: GEI
Predicate Device - 2	K230472 Applicant: Enraf-Nonius, B.V. Trade/Device Name: Sonopuls 190 Regulation Number: 21 CFR 890.5300 Regulation Name: Ultrasonic Diathermy Regulatory Class: Class II Product Code: IMI
Predicate Device - 3	K161628 Applicant: Bonutti Research, Inc. Trade/Device Name: JAS Pulse™ Ultrasonic Therapy Regulation Number: 21 CFR 890.5300 Regulation Name: Ultrasonic Diathermy Regulatory Class: Class II Product Code: IMI

4. Device Description - 807.92(a)(4)

The device is an instrument used for tissue coagulation by means of high-frequency current. It consists of the main unit, two handpieces, foot switch, LCD touchscreen and power cable.

The PLASONIC has two systems (two handpieces) :

1) Radiofrequency (PLAPASS Handpiece)
The device is intended for the removal and destruction of skin lesions and coagulation of tissue. The system is intended for use by trained healthcare professionals in a clinical setting to provide controlled radiofrequency therapy through non-invasive procedure.

2) Ultrasound (SONOPASS Handpiece)

The device is intended for pain relief, reduction of muscle spasms, localized increase in blood flow, increase range of motion of contracted jointed using heat and stretch techniques. The device is designed to deliver therapeutic ultrasound waves, promoting tissue relaxation and aiding in the recovery process for improved patient well-being

5. Indication for Use - 807.92(a)(5)

1) Radiofrequency (Handpiece – PLAPASS)
- Used in the removal and destruction of skin lesions and coagulation of tissue.

2) Ultrasound (Handpiece - SONOPASS)
- Indicated for Pain relief, reduction of muscle spasms, localized increase in blood flow, increase range of motion of contracted jointed using heat and stretch techniques.

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

1) Predicate Device - 1

Characteristics	Proposed Device	Predicate Device - 1	Comparison Comment
510(k) Number	Pending K241099	K223222	-
Manufacturer	Hironic Co., Ltd.	Neauvia North America, Inc	
Trade/Device Name	PLASONIC	Plasma IQ	
Product Code (Regulation Number)	GEI (878.4400), IMI (890.5300)	GEI (878.4400)	
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	100-240VAC, 50/60Hz	110-250VAC, 50/60Hz	Similar
Frequency	41kHz	40kHz	Similar

Max Output Power	0.35W	5W	Different, but the safety of the product has been proven by the Safety Standard Test Report, its performance has been proven by the Performance Test Report, and its effectiveness for its intended use has been proven by the Animal Test Report.
Output Impedance	500Ω	54,000Ω	Different, but the safety of the product has been proven by the Safety Standard Test Report, its performance has been proven by the Performance Test Report, and its effectiveness for its intended use has been proven by the Animal Test Report.
Electrical Safety Standards	Complies with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2	Complies with EN 60601-1, EN 60601-1-2, EN 60601-2-2	Identical

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2) Predicate Device – 2, 3

Characteristics	Proposed Device	Predicate Device - 2	Predicate Device - 3	Comparison Comment
510(k) Number	Pending K241099	K230472	K161628	-
Manufacturer	Hironic Co., Ltd.	Enraf-Nonius, B.V.	Bonutti Research, Inc.	
Trade/Device Name	PLASONIC	Sonopuls 190	JAS Pulse™ Ultrasonic Therapy	
Product Code (Regulation Number)	GEI (878.4400), IMI (890.5300)	IMI (890.5300)	IMI (890.5300)	
Indications for Use	Indicated for Pain relief, reduction of muscle spasms, localized increase in blood flow, increase range of motion of contracted jointed using heat and stretch techniques	Indicated for pain relief, reduction of muscle spasms, localized increase in blood flow, increase range of motion of contracted jointed using heat and stretch techniques	Application of therapeutic ultrasound for: Pain. Pain relief, muscle spasms, and joint contractures. Relief of pain, muscle spasms, and joint contractures that may be associated with: o Adhesive capsulitis, o Bursitis with slight calcification, o Myositis, o Soft tissue injuries, and o Shortened tendons due to past injuries and scar tissues. Relief of pain, muscle spasms, and joint contractures resulting from: o Capsular tightness, and o Capsular scarring.	Identical to Predicate device - 2. Identical to Predicate device - 3. Pain relief, muscle spasms, and joint contractures Localized increase in blood flow. Increased range of motion of contracted joints using heat and stretch techniques.

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			Localized increase in blood flow. Increased range of motion of contracted joints using heat and stretch techniques.	
Weight (Console & Treatment head)	8.1 kg	7 lbs 2oz	0.151 kg (with transducer)	Different, but does not adversely affect safety and effectiveness of the proposed device.
Dimension (W x H x D)	410.8 x 214 x 418.4 mm	6.25 x 5.5 x 8“	10.5 x 6.7 x 2.5cm	Different, but does not adversely affect safety and effectiveness of the proposed device.
Power Supply	100-240VAC, 50/60Hz	100-240 VAC +/- 10%	AC Line 100-240V 50/60 Hz	Identical.
Patient Leakage Current	1 µA typical (requirements IEC < 10 µA)	1 µA typical (requirements IEC < 10 µA)	- Normal Condition 3uA Meets IEC 60601-1, section 8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS - Single Fault condition 5uA Meets IEC 60601-1, section 8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	Identical to Predicate device - 2. Different to Predicate device - 3, but does not adversely affect safety and effectiveness of the proposed device.
Crystal material	PZT	PZT-8 (lead zirconate titanate) piezoceramic material	PZT	Identical.

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Housing Materials and Construction	ABS	ABS	ABS	Identical.
Technology of ultrasound generation	Piezoelectric	Piezoelectric	Piezoelectric	Identical.
Treatment Modes	Continuous Pulsed	Continuous Pulsed	Pulsed & Continuous	Identical.
Beam Type (collimated or divergent)	Divergent	5 cm2 applicator: 1 MHz: collimating 3 MHz: collimating 0.8 cm2 applicator: 1 MHz: collimating 3 MHz: diverging	Collimated	Similar to Predicate device – 2. Different to Predicate device - 3, but does not adversely affect safety and effectiveness of the proposed device.
Transducer Diameter (cm)	2.5cm^2	0.8 cm^2 5cm^2	Diameter: 2.56 cm Area: 5.15 cm^2	Different to each device but does not adversely impact safety and effectiveness of the proposed device.
Frequency	3MHz	1MHz 3MHz	1MHz	Similar to Predicate device – 2. Different to Predicate device - 3, but does not adversely affect safety and effectiveness of the proposed device.
Acoustic Working Frequency and Accuracy (MHz)	3MHz± 10%	5 cm^2, 0.8 cm^2 and 1 MHz: 0.98 MHz ± 5% 3 MHz: 3.1 MHz ± 5%	1.0 MHz ± 10%	Similar to Predicate device – 2. Different to Predicate device - 3, but does not adversely affect safety and effectiveness of the proposed device.
Effective Radiating Area	1.485 cm^2	5 cm^2 applicator: 5 cm^2	1.133 cm2 ± 20%	Similar to Predicate device - 3.

		0.8 cm² applicator: 0.8 cm²		Different to Predicate device - 2, but does not adversely impact safety and effectiveness of the proposed device and complies with IEC 60601-2-5.
Beam Non-uniformity Ratio	3.9367:1 maximum	6:1 maximum	2.5 ± 30%	Different, but does not adversely impact safety and effectiveness of the proposed device and complies with IEC 60601-2-5.
Output Mode of Ultrasound Head	Continuous mode: 1 Pulsed Mode: 4	2	2	Similar to each device.
Maximum Timer Setting	10 minutes	10 minutes	15 minutes	Identical to Predicate device - 2. Different to Predicate device - 3, but does not adversely impact safety and effectiveness of the proposed device and complies with IEC 60601-2-5.
Output power (Intensity)	0 - 0.18W/cm^2	0 - 3.0W/cm^2	Continuous (High): 1.4 W/ cm2 Pulsed (Low): 0.7 W/ cm2 (all values ± 20%)	Different but does not adversely impact safety and effectiveness of the proposed device and complies with IEC 60601-2-5.
Pulse Frequency	2Hz± 10%	16Hz, 48Hz, 100Hz +/- 1%	-	Different to each device, but does not adversely affect safety and effectiveness of the proposed device.

Temporal Max Power (W) – [for pulsed]	Duty cycle 25%: 0.12W Duty cycle 50%: 0.14W Duty cycle 62.5%: 0.21W Duty cycle 75%: 0.20W	5 cm^2 applicator: duty cycle 5-50%: 15W duty cycle 80%: 12W 0.8 cm^2 applicator: duty cycle 5-50% 2.4 W duty cycle 80%: 2 W	0.79W	Different to each device but does not adversely impact safety and effectiveness of the proposed device and complies with IEC 60601-2-5.
Temporal Max Power (W) – [for continuous]	0.21W	5 cm^2 applicator: 10 W 0.8 cm^2 applicator: 1.6 W	1.59W	Different but does not adversely impact safety and effectiveness of the proposed device and complies with IEC 60601-2-5.
Maximum Value of the Output Power (Rated Output Power) and Accuracy (W)	0.21W± 20%	5 cm^2 applicator: 10 W ± 20% 0.8 cm^2 applicator: 2 W ± 20%	Continuous (High): 1.59W Pulsed (Low): 0.79W (all values ± 20%)	Different but does not adversely impact safety and effectiveness of the proposed device and complies with IEC 60601-2-5.
Peak Temperature Rise vs. Time and Tissue Depth to Maximum Treatment Time (for fixed Treatment Head Placement) (deg C)	Elevation of temperature raise 10.5 ℃ for 10 minutes 3.0 MHz, 0.21 W Effective depth 0.5 cm	Elevation of temperature raise 4.8ºC for 10 minutes 1.0MHz, 2.0W Effective depth 2.5cm Elevation of temperature raise 5.8ºC for 3 minutes 3.0MHz, 2.0W Effective depth 0.8cm	-	Different to each device, but does not adversely affect safety and effectiveness of the proposed device.
Maximum Patient Contact Surface Temperature of Treatment Head under Simulated fixed Treatment Head Placement) (degC) or Actual Use Conditions for all Operating Conditions	1.485 cm^2 applicator < 45 deg C	5 cm^2 applicator <43 deg C 0.8 cm^2 applicator <34 deg C	Transducer surface does not exceed 43 °C when measured under test conditions 201.11.1.3.101.1 as stated in IEC 60601-2-5.	Different to each device, but does not adversely affect safety and effectiveness of the proposed device.

(Continually operated for maximum treatment time) (deg C)				
Penetration Depth	3 MHz: 1.1 cm	1MHz: 2.5cm 3MHz: 0.8cm		Similar to Predicate device - 2.
Electrical Safety Standards	Complies with IEC 60601-1, IEC 60601-1-2, IEC60601-2-5	Complies with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-5	Complies with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-5	Identical.

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7. Non-clinical tests submitted - 807.92(b)(1)

- 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/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 60601-2-5:2009 for use with IEC 60601-1:2005, COR1:2006 COR2:2007, AMD1:2012 Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment:
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests is evaluated in accordance with the FDA-recognized consensus standard
- IEC 60601-1-6:2010 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability is evaluated in accordance with the FDA-recognized consensus standard
- IEC 62304:2006 Medical device software – Software life cycle processes is evaluated according to the FDA-recognized consensus standard
- IEC 62366-1:2015 Medical devices – 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
- 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.

8. Clinical tests submitted - 807.92(b)(2)

No clinical test was performed.

9. Conclusions drawn from clinical and non-clinical tests submitted

The PLASONIC is substantially equivalent to its predicate device and 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.