April 6, 2026

Hironic Co., Ltd.
Byoungkook Kim
RA/QA Division
Contact Address

Re: K260397
Trade/Device Name: SYNERJET PRO (SP-1002); InPhiuse (SP-1002); WOWJET (SP-1002)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 20, 2026
Received: February 9, 2026

Dear Byoungkook Kim:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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: 2026.04.06 23:25:32 -04'00'

James Jang, Ph.D.
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.	K260397

Please provide the device trade name(s).

SYNERJET PRO (SP-1002);
InPhiuse (SP-1002);
WOWJET (SP-1002)

Please provide your Indications for Use below.

The device is used in 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 (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #:	510(k) Summary	Prepared on: 2026-04-03

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Hironic Co., Ltd.
Applicant Address	19F, U-TOWER, 767, Sinsu-ro, Suji-gu Yongin-si Gyeonggi-do 16827 Korea, Republic of
Applicant Contact Telephone	+82-31-525-7000
Applicant Contact	Mr. Byoungkook Kim
Applicant Contact Email	ra@hironic.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SYNERJET PRO (SP-1002); InPhiuse (SP-1002); WOWJET (SP-1002)
Common Name	Electrosurgical cutting and coagulation device and accessories
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number	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
K241099	PLASONIC	GEI

Device Description Summary

21 CFR 807.92(a)(4)

The device is used in the removal and destruction of skin lesions and coagulation of tissue. The device consists of the main unit, LCD touch screen, handpiece (PS), foot switch, accessories, and power cable.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The device is used in the removal and destruction of skin lesions and coagulation of tissue.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The device (SYNERJET PRO (SP-1002); InPhiuse (SP-1002); WOWJET (SP-1002)) indication for use is present within the indications for use of the predicate device. Specifically, the radiofrequency PLAPASS handpiece of the PLASONIC device.

SYNERJET PRO (SP-1002); InPhiuse (SP-1002); WOWJET (SP-1002) Indication for Use: The device is used in the removal and destruction of skin lesions and coagulation of tissue.

Predicate Device Indication for Use: 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.

Technological Comparison 21 CFR 807.92(a)(6)

The device (SYNERJET PRO (SP-1002); inPhiuse (SP-1002); WOWJET (SP-1002)) has same or similar technological characteristics with predicate device, such as mode of operation, output, frequency and electrical safety standards

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-Clinical Test was conducted evaluation of coagulation and temperature in ex vivo following the device as requested Hironic Co., Ltd. by third-party laboratory.

The results confirmed that, when the test device was applied to the target region using the PS handpiece with the PS Tip and PS Brush under various power output conditions, the intended temperature increase and coagulation area were successfully achieved. Based on these results, this performance evaluation supports the feasibility of applying the device to further investigations involving human tissue.