October 19, 2021

Hironic Co., Ltd.
Seo Ji Yeong
Regulatory Affairs
19F,767, Sinsu-Ro, Suji-Gu
Yongin-Si, Gyeonggi-do 16827
Korea, Republic Of

Re: K201773
Trade/Device Name: PICOHI
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 15, 2021
Received: September 15, 2021

Dear Seo Ji Yeong:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Purva Pandya
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)*
K201773

Device Name
PICOHI

Indications for Use *(Describe)*
The PICOHI is indicated for the following at the specified wavelength:

- 1064nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple.
- 532nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.
- Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K201773

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, 767, Sinsu-ro, Suji-gu, Yongin-si, Gyeonggi-do, 16827, Republic of Korea
Phone Number	+82-31-525-7000
Fax Number	+82-31-525-7010
Contact Person	Jiyeon, Woo
Contact Information	m. +82-10-8725-4345 e. ra@hironic.com
Preparation Date	2021/09/10

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

Device Trade Name	PICOHI
Common Name	Laser Surgical Instrument
Classification Name	Powered Laser Surgical Instrument
Product Code	GEX
Regulation Number	21 CFR § 878.4810
Regulatory Class	Class II
Review Panel	General & Plastic Surgery

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

Predicate Devices for laser	PICOWAY(K191685) This predicate devices have not been subject to a design-related recall.

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

The PICOHI is a solid-state laser capable of delivering energy at wavelengths of 1064nm, 532nm at extremely short duration in the range of 275-300ps. The laser system contains one 1064nm (Nd:YAG) laser head which is used to create the 1064nm picosecond wavelength which can be frequency-doubled to 532nm as desired. The outputs of the two lasers are designed to be co-linear on the laser rail so that their beam paths are identical as they exit the laser system. This allows the use of a single delivery system which can output either the 1064nm or 532nm wavelengths. All these energies are delivered through an articulated arm and corresponding handpiece.

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

The PICOHI is indicated for the following at the specified wavelength:

- 532 nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.
- 1064 nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple.

The PICOHI is also indicated for treatment of benign pigmented lesions for Fitzpatrick Skin Types I-IV.

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

(1) Predicate device

	Proposed Device	Predicate Device
510(k) Number	K201773	K191685
Manufacturer	Hironic Co., Ltd.	Candela Corporation
Device Name	PICOHI	PICOWAY
Classification Name	Powered laser surgical instrument	Powered laser surgical instrument
Indication for use	The PICOHI is indicated for the following at the specified wavelength: • 532 nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange. • 1064 nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple. • Treatment of benign pigmented lesions for Fitzpatrick skin types I-IV.	The PicoWay laser system is indicated for the following at the specified wavelength: • 532 nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange. • 730 nm: Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue. • 785 nm: Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue. • 1064 nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple. • The Picoway laser system is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV. • The Resolve handpiece (1064 nm) is also indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V. • The Resolve handpieces (532 nm HE, 532 nm, 1064 nm) are also indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV • The Resolve Fusion handpiece (1064 nm) is indicated for the treatment of

		wrinkles as well as benign pigmented lesions in Fitzpatrick Skin Types I-IV • The Resolve Fusion handpiece (532 nm) is indicated for the treatment of benign pigmented lesions in Fitzpatrick Skin Types I-IV
Laser Source	Nd:YAG	Nd:YAG
Wavelength	532/1064 nm	532/1064 nm
Max. Fluence	16.00 J/cm^2	12.5 J/cm^2
Pulse Width	275-300 ps	375-450 ps
Max. Repetition	10 Hz	10 Hz
Spot Size	1.5-13 mm • Zoom (532 nm): 1.5-7.5 mm • Zoom (1064 nm): 10 mm • Collimated (1064 nm): 10 mm • VMLA (532/1064 nm): 13 mm • ZMLA (532/1064 nm): 12 mm • DOE (532/1064 nm): 10 mm	2-10 mm
Rated Input	220-240 VAC, 50/60 Hz, 20 A	200-240 VAC, 50/60 Hz, 30 A

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

- Basic safety and essential performance of the PICOHI is evaluated in accordance with IEC 60601-1:2012.
- Effect to the device by electromagnetic disturbances is evaluated in accordance with the FDA-recognized consensus standard, IEC 60601-1-2:2014.
- Safety of laser products are evaluated in accordance with IEC 60825-1:2014.
- General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability is evaluated in accordance with the FDA-recognized consensus standard, IEC 60601-1-6:2013.
- Particular Requirements for Basic Safety and Essential Performance of Low Intensity Laser System are evaluated in accordance with IEC 60601-2-22:2012.
- Risk management is recorded in the reference of ISO 14971:2007.
- The software for PICOHI is verified and validated in accordance with its moderate level of concern. Software life cycle processes are evaluated according to the FDA-recognized consensus standard, IEC 62304:2006.
- Application of usability engineering to medical devices is evaluated in accordance with IEC 62366:2007.

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

No clinical performance testing was performed.

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

The PICOHI and the predicate devices have the same intended use with similar indications for use.
The PICOHI Laser System presents the same or similar technological characteristics as its predicate devices, including the laser type, wavelengths, device design, pulse width, frequency, spot sizes and system components. PICOHI is substantially equivalent to its predicate devices 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 testing shows that the device is safe to use and meets required standards. These non-clinical tests show that the PICOHI can safely deliver laser energies to the patient as intended. The device meets design specifications as well as performance requirements. Any minor differences do not present any new types of safety or effectiveness questions since the PICOHI parameters are similar to or within the range of the predicates. Further, PICOHI performance has been demonstrated in non-clinical investigations, and results confirm the safety and performance of the device. The PICOHI device and its predicates all operate with the same mechanism of action based on selective photothermolysis of pigment particles using laser energy. Therefore, the PICOHI has the same intended use and similar indications for use, technological characteristics, and principles of operation as the predicate devices. The PICOHI is substantially equivalent to the predicate devices.

10. Summary of Substantial Equivalence

PICOHI is substantially equivalent to its predicate devices 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 testing shows that the device is safe to use and meets required standards. These non-clinical tests show that the PICOHI can safely deliver laser energies to the patient as intended. The device meets design specifications as well as performance requirements.
Any minor differences in the human interface and accessories design do not raise any new types of safety and effectiveness issues, as verified by performance testing.
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.

Best Regard,

September 10, 2021

Regulatory Affair Manager, R&D Dept.