September 14, 2018

HIRONIC Co., Ltd.
℅ Mina Joo
Assistant Manager
BT Solutions, Inc.
Unit 502, 148 Yeoksam-ro
Seoul, 06249 Kr

Re: K173676
Trade/Device Name: A-fit
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: August 9, 2018
Received: August 15, 2018

Dear Mina Joo:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
Not Available K173676

Device Name
A-FIT

Indications for Use *(Describe)*

Main Hand Piece
For use in dermatology: incision, excision, ablation, and vaporization with hemostasis of soft tissue,
Treatment of back acne
Treatment of atrophic acne scars
Treatment of facial wrinkles
Treatment of mild to moderate acne vulgaris
Treatment of Sebaceous Hyperplasia

Radio Frequency Hand piece
The RF Hand piece energy is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation.

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.

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5. 510(k) Summary

1. General Information

Applicant/Submitter:	Hironic Co., Ltd.
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Contact Person:	Mina Joo, BT Solutions, Inc.
Address:	Unit 502, 148 Yuksamro, Gangnam-gu, Seoul, Republic of Korea Tel) +82.2.538.9140 Email) smanager@btsolutions.co.kr
Preparation Date:	September – 13 – 2018

2. Device Name and Code

Device Trade Name:	A-FIT
Common Name:	Laser Surgical Unit
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology Electrosurgical cutting and coagulation device and accessories
Product Code:	GEX, PBX
Regulation Number:	878.4810 878.4400
Classification:	Class II
Review Panel:	General & Plastic Surgery (ODE)

3. Technical Characteristics in Comparison to Predicate Devices

A-FIT is substantially equivalent to the following legally marketed predicate devices. We identified two predicate devices under product code GEX for Laser hand piece and PBX for RF hand piece respectively.

1) Predicate device for Laser – K041242

	Predicate Device	Proposed Device
510(K) Number	K041242	N/A
Manufacturer	CANDELA CORP.	Hironic Co., Ltd.
Device Name	CANDELA SMOOTHBEAM LASER SYSTEM	A-FIT
Clearance Date:	April 23, 2004	N/A
Classification / Regulation	Class II / (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)	Class II / (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Product Code	GEX	GEX
Light Source	Diode Laser	Diode Laser
Wavelength – Beam radiation	1450 nm	1450 nm ± 10%
Wavelength – Beam pointing	Unknown	635 nm ± 10 %
Indications for Use / Intended Use	For use in dermatology: incision, excision, ablation, and vaporization with hemostasis of soft tissue, Treatment of back acne Treatment of atrophic acne scars Treatment of facial wrinkles Treatment of mild to moderate acne vulgaris Treatment of Sebaceous Hyperplasia	For use in dermatology: incision, excision, ablation, and vaporization with hemostasis of soft tissue, Treatment of back acne Treatment of atrophic acne scars Treatment of facial wrinkles Treatment of mild to moderate acne vulgaris Treatment of Sebaceous Hyperplasia
Intended for	Prescription Use	Prescription Use
Maximum Pulse Duration (Pulse Width)	210 ms	Total 250 ms (62.5 ms X 4) ± 10% Total 250 ms (4.17 ms X 60) ± 10%
Maximum laser output (J/cm^2)	8-25 J/cm^2	4 J/cm^2 - 13 J/cm^2 ± 20% (Soft and Normal modes)
Maximum laser output - Beam pointing	Unknown	< 5 Mw
Laser radiation range – Beam radiation	4mm, 6mm	6mm ± 20%
Laser radiation range – Beam pointing	Unknown	6mm ± 20%
Pulse Repetition Rate (Hz)	1 Hz	Normal Mode: 4 Hz (62.5ms x 4 pulse) Soft Mode: 60 Hz (4.17ms x 60 pulse)
Interface	Touch Screen	Touch Screen
Beam Delivery System	Handpiece	Handpiece
Laser transmission method	Diode	Optical Fiber
Activation	Via Foot switch	Via Footswitch
Cooling System	Integrated-Spray Duration Control / Canister Counter	Cryogen Cooling Device 10 ms ~ 50 ms

	2 ~ 60 ms	
Electrical Requirements	115/230 VAC 50/60 Hz	110 V 60 Hz / 2-1A, 600 VA
Weight	40 lbs (18 kg)	21.8 lbs (48 kg)
Dimension	17" H x 22" W x 20" D (431.8 x 558.8 x 508 mm)	350 x 500 x 857 mm
Operation time	10 minutes	10 minutes

2) Predicate device for RF – K133739

	Predicate Device	**Proposed Device**
510(K) Number	K133739	N/A
Manufacturer	Cutera, Inc.	Hironic Co., Ltd.
Device Name	truSculpt	A-FIT
Clearance Date:	September 5, 2014	N/A
Classification / Regulation	Class II / (21 CFR § 878.4400 Electrosurgical Cutting and Coagulation Device and Accessories)	Class II / (21 CFR § 878.4400 Electrosurgical Cutting and Coagulation Device and Accessories)
Product Code	PBX	PBX
Indications for Use / Intended Use	The truSculpt RF energy is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation. *The truSculpt massage device is intended to provide a temporary reduction in the appearance of cellulite.	The RF Hand piece energy is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation.
Intended for	Prescription Use	Prescription Use
Massage	Yes – as a separate handpiece	N/A
Treatment activation	Via Finger switch	Via Footswitch
Electrode shape	Square or Rectangular	Circle
RF frequency	300 kHz – 50 MHz	550 kHz, 700 kHz, 1000 kHz
RF type	Bipolar/Monopolar	Bipolar
Max RF power	Max 300 W	12 Watt (240 mA, 48.0 Vrms, 200 Ω, RET)

*A-FIT does not include the massaging device. However, the A-FIT's RF hand piece share the same intended use of the predicate device (truSculpt's RF energy).

4. Device Description

A-FIT consists of Laser diode and high-frequency (RF) stimulator. It can be used for incision, destruction and removal of skin tissue by illuminating a 1450 nm wavelength laser on the skin tissue. In addition, the RF energy can be used to relieve pain.

Laser surgical unit, diode: Specifically, a 1450 nm wavelength laser is absorbed into the skin to be transformed into thermal energy, which then induces incision, destruction and removal of skin tissues. Laser is sent out through the power unit equipped inside the Main Body to oscillate the laser diode, and the user uses the touch LCD in the Main Body to set the output parameters while controlling laser radiation through the foot switch. At this point, a coolant is sprayed from the end of the hand piece to protect skin from the heat generated by the radiated laser, resulting in a reduction in skin irritation and pain.

Electrosurgical system, general-purpose: The operating concept of the electrosurgical unit is to let the high frequency (RF) energy flow through the electrodes of the hand piece to use the load or heat generated by contact resistance, resulting in a coagulant activity on the cell tissues.

5. Indications / Intended Use

Main Hand piece
For use in dermatology: incision, excision, ablation, and vaporization with hemostasis of soft tissue,
Treatment of back acne
Treatment of atrophic acne scars
Treatment of facial wrinkles
Treatment of mild to moderate acne vulgaris
Treatment of Sebaceous Hyperplasia

Radio Frequency Hand piece
The RF Hand piece energy is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation.

6. Performance Data

Non-clinical tests: Testing conducted on the A-FIT shows that it refers to the relevant mandatory performance standards for laser products 21 CFR 1040.10 and 1040.11. Other performance, such as electromagnetic compliance, etc, were tested using following consensus standards:

- Basic safety and essential performance of the A-FIT was tested and evaluated according to IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1:2012 reprint).
- Effect to the device by electromagnetic disturbances were tested and evaluated according to the FDA-recognized consensus standard, IEC 60601-1-2 Edition 3: 2007-03.
- Safety of laser products is evaluated according to IEC 60825-1:2014 (Third Edition).
- General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability was tested and evaluated according to the FDA-recognized consensus standard, IEC 60601-1-6 Edition 3.1 2013-10.
- Particular Requirements for The Basic Safety and Essential Performance of High Frequency Surgery Equipment And High Frequency Surgical Accessories was tested and evaluated according to IEC 60601-2-2:2009 (Fifth Edition) + C1:2014.

- Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment was tested and evaluated according to IEC 60601-2-22:2007 (Third Edition) +A1:2012.
- Risk management was recorded by referring to ISO 14971.
- The software for A-FIT has been verified and validated based on its moderate level of concern. Software life cycle processes was evaluated according to the FDA-recognized consensus standard, IEC 62304:2006.
- Application of usability engineering to medical devices was tested and evaluated according to IEC 62366:2007.
- Biocompatibility of A-FIT was documented referred to ISO 10993-1:2009, ISO 10993-5:2009, and 10993-10:2010.

7. Substantial Equivalence

The intended use of the A-FIT is within the scope of the predicate devices. A-FIT, from both a design and clinical perspective, uses similar or identical technology as the cited predicate devices and has the same intended uses. Based upon the predicted overall performance characteristics for the A-FIT, Hironic Co., Ltd. believes that no significant differences exist in usage of its underlying technological principles between A-FIT and the cited predicate device.

8. Conclusions

On the basis of the information provided in this Summary, A-FIT believes that A-FIT is substantially equivalent to legally commercialized predicate devices for the purposes of this 510 (k) submission.