December 1, 2020

HIRONIC Co., Ltd
% Sanghwa Myung
Regulatory Affairs Consultant
E&M
D-1474, 230, Simin-daero, Dongan-gu
Anyang-Si, 14067 Kr

Re: K192970
Trade/Device Name: Slimus
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use 878.5650
Regulatory Class: Class II
Product Code: PKT, ISA
Dated: March 12, 2020
Received: March 17, 2020

Dear Sanghwa Myung:

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
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

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)*

K192970

Device Name
SLIMUS

Indications for Use *(Describe)*

The SLIMUS is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, and thighs.
Vibrator installed inside each hand-piece and operable only in non-laser output condition is intended for relief from minor muscle aches and pains.

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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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

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	**Sang Hwa, Myung**
Contact Information	**D-1474, 230, Simin-daero, Dongan-gu, Anyang-si, Gyeonggi-do, 14067, Republic of Korea m. +82-10-4952-6638, e. mshenmc@gmail.com, f. 031-388-9263**

Date 510(k) summary prepared: October 26th, 2020

2. Device Name and Product Code

Device Trade Name	**SLIMUS**
Common Name	**Low Intensity Laser System**
Classification Name	**Laser for disruption of adipocyte cells for aesthetic use**
Product Code	**PKT**
Regulation Number	**21 CFR 878.5400 - Low Intensity Laser System**
Regulatory Class	**II - Low Intensity Laser System**
Review Panel	**General & Plastic Surgery (ODE)**

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

Predicate Device	**Sculpsure (K171111)**

4. Device

The SLIMUS device incorporates a laser system that emits a 1060 nm wavelength using a diode laser. Laser radiation is emitted from the laser main unit to the device's handpieces through the handpiece fibers. The device is used to non-invasively reduce the size of the waist of overweight patients with a Body Mass Index (BMI) of less than 30 (kg/m^2). A vibrator function is installed inside of each hand-piece and operable only in non-laser output mode. The device's handpieces are fixed to a belt which then combined provide mechanical vibration to the patient in order provide relief from minor muscle aches and pains.

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5. Indication for Use

The SLIMUS is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass Index (BMI) of30 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, and thighs. Vibrator installed inside each hand-piece and operable only in non-laser output condition is intended for relief from minor muscle aches and pains..

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6. Summary of the Technological Characteristics of the Device Compared to the Predicate

	Proposed SLIMUS	Predicate SculpSure
510(k) Number	K192970	K171111
Manufacturer	Hironic Co., Ltd.	Cynosure, Inc.
Lipolysis Method	Heat-assisted	Heat-assisted
Device Type	Diode Laser	Diode Laser
Indication for use	The SLIMUS is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, and thighs. Vibrator installed inside each hand-piece and operable only in non-laser output condition is intended for relief from minor muscle aches and pains.	The Cynosure SculpSure™ is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, and thighs.
Wavelength	1060 ± 20 nm (infrared)	1060 ± 20 nm (infrared)
Spot Size	4 x 6 cm^2 on each of the Applicator heads	4 x 6 cm^2 on each of the Applicator heads
Pulse Width (laser On time)	CW	CW
Power Density	Up to 1.4 W/cm^2	Up to 1.4 W/cm^2
Attachment to patient	Belt	Belt
Rated Input	AC 220-230 V, 4 kVA	AC 200-240 V, 20 A

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

-. Basic safety and essential performance of the SLIMUS 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 is 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.

-. 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.

-. Biocompatibility of SLIMUS is documented in the reference of ISO 10993-1:2009, ISO 10993-5:2009, and 10993-10:2010.

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8. No Clinical performance testing was performed.

9. Discussion of non-clinical testing.

The non-clinical data for the SLIMUS device, including bench testing, electrical medical device safety, electromagnetic field compatibility, laser safety, biocompatibility, hardware, and software documentation together support that the device can perform as intended.

10. Conclusions

The SLIMUS device shares the same intended use and similar technological characteristics with the predicate device. These do not raise new types of questions regarding safety and efficacy for the SLIMUS when compared to the predicate. Based on its technical characteristics, indications for use, and performance data, the SLIMUS device is considered to be substantially equivalent to the predicate device.