March 7, 2025

Daeju Meditech Engineering Co., Ltd.
% Lee April
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

Re: K242207
Trade/Device Name: Noable Laser
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: February 7, 2025
Received: February 7, 2025

Dear Lee April:

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,

YAN FU -S Digitally signed by YAN FU -S
Date: 2025.03.07 09:29:02 -05'00'

for Tanisha Hithe
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)*

K242207

Device Name

NOABLE LASER

Indications for Use *(Describe)*

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

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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510(k) Summary

Submitter
DAEJU MEDITECH ENGINEERING CO., LTD.
SEONGUN KIM
#501-504, HausD Sejong Tower,
26, Seongsu-il-ro 10-gil, Seongdong-gu
Seoul, Republic of Korea 04793
Email: globalsales@daejumedi.co.kr
Phone: +82-2-2208-0905

Official Correspondent
Withus Group Inc.
April Lee
106 Superior,
Irvine, CA
USA 92620
Email: withus6664@gmail.com
Phone: +1-909-274-9971

Device Information

- Trade Name: NOABLE LASER
- Common Name: Laser Surgical Instrument
- Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Product Code: GEX
- Panel: General & Plastic Surgery
- Regulation Number: 21 CFR §878.4810
- Device Class: Class II
- Date prepared: 03/06/2025

Predicate Device

Primary Predicate
K173676, A-fit manufactured by Hironic Co., Ltd.
Reference
K041242, CANDELA SMOOTHBEAM LASER SYSTEM manufactured by CANDELA CORP.

Indications for 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

Device Description

NOABLE LASER is a laser surgical instrument used during treatment where the laser 1450nm wavelength generated from the diode laser module. It can be used for incision, destruction and removal of skin tissue by illuminating a 1450 nm wavelength laser on the skin tissue.
Based on state-of-the-art diode laser technology, the system offers many advantages, including the combination of the effective wavelengths, excellent pulse characteristics, and unique dynamic cooling device (DCD) and compact instrument. Laser is sent out through the diode laser module equipped inside the Main body to oscillate the laser, and the user uses the touch LCD in the Main body and hand-piece to set the output parameters while controlling laser radiation through the foot switch and hand-piece 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.

Summary of Technological Characteristics

ITEM	PROPOSED DEVICE	PREDICATE DEVICE	REFERENCE DEVICE	Remark
	NOABLE LASER	A-Fit	CANDELA SMOOTHBEAM LASER SYSTEM	
K number	K242207	K173676	K041242	
Product Code	GEX	GEX	GEX	Same
Regulation	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Indications for 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	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.	The Candela Smoothbeam Laser is indicated for the following uses: 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	Same
Light source	Diode Laser	Diode Laser	Diode Laser	Same
Wavelength-Beam radiation	1450nm ± 10%	1450nm ± 10%	1450nm	Same
Wavelength – Beam Pointing	635nm ± 10%	635nm ± 10%	Unknown	Same

ITEM	PROPOSED DEVICE	PREDICATE DEVICE	REFERENCE DEVICE	Remark
Intended for	Prescription Use	Prescription Use	Prescription Use	Same
Maximum laser output	4 J/cm2 - 12 J/cm2 ± 20% (STAMPING mode) 4 J/cm2 - 8 J/cm2 ± 20% (TONING mode)	4 J/cm2 - 13 J/cm2 ± 20% (Soft and Normal modes)	8-25 J/cm2	Similar
Maximum laser output – Beam pointing	< 5 Mw	< 5 Mw	Unknown	Same
Maximum Pulse Duration (Pulse Width)	Total 250 ms(62.5 ms X 4) ± 10% Total 250 ms (4.17 ms X 60) ± 10%	Total 250 ms (62.5 ms X 4) ± 10% Total 250 ms (4.17 ms X 60) ± 10%	210 ms	Same
Laser radiation range – Beam radiation	4mm, 6mm ± 20%	6mm ± 20%	4mm, 6mm	Same
Pulse Repetition Rate (Hz)	STAMPING Mode: 4Hz (62.5 ms x 4 pulse) TONING Mode: 60 Hz (4.17ms x 60 pulse)	Normal Mode: 4 Hz (62.5ms x 4 pulse) Soft Mode: 60 Hz (4.17ms x 60 pulse)	1 Hz	Similar
Interface	Touch Screen	Touch Screen	Touch Screen	Same
Beam Delivery System	Handpiece	Handpiece	Handpiece	Same
Laser transmission method	Optical Fiber	Optical Fiber	Diode	Same
Activation	Via Footswitch and hand-piece switch	Via Footswitch	Via Footswitch	Analysis 1
Cooling System	Cryogen Cooling Device 25 ms ~ 50 ms (5 ms ~ 10 ms x 5)	Cryogen Cooling Device 10 ms ~ 50 ms	Integrated-Spray Duration Control / Canister Counter 2 ~ 60 ms	Analysis 2
Electrical Requirements	100-240VAC, 50/60Hz, 600VA	110 V 60 Hz / 2-1A, 600 VA	115/230 VAC 50/60Hz	Analysis 3
Weight	36 kg	48 kg	40 lbs (18kg)	

ITEM	PROPOSED DEVICE	PREDICATE DEVICE	REFERENCE DEVICE	Remark
Dimensions	420 x 420 x 1,560mm	350 x 500 x 857mm	431.8 x 558.8 x 508mm	
Operation time	10 minutes	10 minutes	10 minutes	Same

The subject and primary predicate device (K173676) are similar in indications, design, technology, functions, and principle of operation.

The differences between the subject and primary predicate are discussed as below:

Analysis 1 – Activation
The Activation of the proposed device is different from predicate device. However, the activation is only concerned with the operation method of the product and this difference will not raise any issues in safety and effectiveness. Thus, the proposed device is determined to be substantially equivalent with predicate device.

Analysis 2 - Cooling System
The proposed device has a different Duration of Cooling system from the predicate device. Cooling System (HFC-134a is raw material of Cooling System) is same. And duration of cooling system of proposed devices is within the duration of cooling system of predicate device. Thus, the proposed device is determined to be substantially equivalent with predicate device.

Analysis 3 - Electrical Requirements, Weight and Dimensions
The Electrical Requirements, Weight and Dimensions for the subject device are different from predicate device. However, the difference is just in electrical and physical specification and this difference will not raise any issues in safety and effectiveness. Thus, the difference is considered would not raise any issues in safety and effectiveness. And the proposed device has passed the IEC 606061-1, IEC 60601-1-22, IEC 60825-1 test and performance test in IEC 60601-1 test, the safety and performance of the product can be ensured.

Non-clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specification as was substantially equivalent (SE) to the predicate device.

Biocompatibility Testing

The biocompatibility evaluation for the subject device was conducted in accordance with the guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatible testing including cytotoxicity, Sensitization and Irritation are conducted according to the ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Biocompatibility testing of NOABLE LASER is as below;

a) ISO 10993-5:2009 - Biological Evaluation of Medical Devices - Part 5: Tests for in vitro cytotoxicity

b) ISO 10993-10:2021 - Biological Evaluation of Medical Devices - Part 10: Tests for skin sensitization, 6.5 Guinea pig maximization test(GPMT)

c) ISO 10993-23:2021 - Biological Evaluation of Medical Devices - Part 23: Tests for irritation, 7.2 Animal irritation test by skin exposure

Electrical Safety and electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on Laser Surgical Instrument. The device complies with the following standards

- IEC 60601-1: 2005+A2:2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
- 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
- IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements

Particular Performance Testing

Performance testing was conducted on the device according to the following standard:

- IEC 60601-1: 2005+A2:2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
- IEC 60601-2-22:2019 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

Software Verification and Validation Testing

The software for this device was considered as a "Moderate" level of concern. Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Accuracy Testing

The accuracy test was conducted to verify that the energy output and laser radiation range of the proposed laser system do not deviate the tolerance of the setting value of energy output or the fixed value of range. The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Clinical Testing
Not applicable.

Conclusion
Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices.