July 12, 2022

MEDMIX Co., Ltd.
% Jonghyun Kim
Chief Consultant
GMS Consulting
4th Floor, Digital Cube, 34, Sangamsan-ro
Seoul, Mapo-gu 03909
Korea, South

Re: K221083
Trade/Device Name: Smartlux Mini
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, ILY
Dated: April 11, 2022
Received: April 13, 2022

Dear Jonghyun 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 (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,

Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221083

Device Name
SMARTLUX MINI

Indications for Use *(Describe)*
Blue (415-425nm), is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

Red (630-640nm) and Infrared (820-830nm) Combination is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

Combination of Infrared (820-830nm) and Yellow (585-595nm) is intended to emit energy in the IR and visible spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

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

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

April 11, 2022

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: MEDMIX Co., Ltd
- Address: B-707 Smartvalley, 30, Songdomirae-ro, Yeonsu-gu, Incheon, Republic of Korea
- Contact Name: Yunseok Yu
- Telephone No.: +82 10-9487-8160
- Email Address: ysyu@medmix.co.kr
- Registration No.: K221083

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

510(k) Number	K221083
Trade/Device/Model Name	SMARTLUX MINI
Product Name	Phototherapy Unit
Device Classification Name	Powered Laser Surgical Instrument
Regulation Number	21 CFR 878.4810 / 21 CFR 890.5500
Classification Product Code	GEX (Primary), ILY (Secondary)
Device Class	2
510(k) Review Panel	General & Plastic Surgery / Physical Medicine

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate device within this submission is shown as follow;

Predicate Device

510(k) Number	K192755
Trade/Device/Model Name	Soli-Lite LG4 Galileo
Product Name	Phototherapy Unit
Device Classification Name	Powered Laser Surgical Instrument
Regulation Number	21 CFR 878.4810 / 21 CFR 890.5500
Classification Product Code	GEX (Primary), ILY (Secondary)
Device Class	2
510(k) Review Panel	General & Plastic Surgery / Physical Medicine

5. Description of the Device [21 CFR 807.92(a)(4)]

The Photo-Therapy Device SMARTLUX MINI is a portable device which uses specific wavelengths of light, produced by light emitting diodes (LEDs).

The device produces light in the following regions of the light spectrum:

- Red (630-640nm)
- Blue (415-425nm)
- Yellow (585-595nm)
- Infra-red (820-830nm)

This device's main components are the stand, the head, color touch screen, and the power supply. User interface software allows the operator to access and control all device functions.

6. Indications for use [21 CFR 807.92(a)(5)]

Blue (415-425nm), is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

Red (630-640nm) and Infrared (820-830nm) Combination is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

Combination of Infrared (820-830nm) and Yellow (585-595nm) is intended to emit energy in the IR and visible spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

7. Technological Characteristics (Equivalence to Predicate Device) [21 CFR 807.92(a)(6)]

Provided below is a table summarizing and comparing the technological characteristics of the SMARTLUX MINI and the predicate device:

	Subject Device	**Predicate Device**
Product Name	Phototherapy Unit	Phototherapy Unit
Model Name	SMARTLUX MINI	Soli-Lite LG4 Galileo
Manufacturer	MEDMIX Co., Ltd.	Silhouet-Tone Corporation
Indications for Use	Blue (415-425nm), is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. Red (630-640nm) and Infrared (820-830nm) Combination is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. Combination of Infrared (820-830nm) and Yellow (585-595nm) is intended to emit energy in the IR and visible spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.	Blue (410-415nm), is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. Red (620-633nm) and Infrared (820-830nm) Combination is intended to emit energy in the red and infra-red region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. Combination of Infrared (820- 830nm) and Yellow (585-595nm) is intended to emit energy in the IR and visible spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.
Submission Number	K221083	K192755
Product Code	GEX (Primary), ILY (Secondary)	GEX (Primary), ILY (Secondary)
Device Class	2	2
Configuration	Portable	Portable
Components	Stand, Head, Color touch screen, Power supplier	Main frame, irradiator, lifting stand
Wavelength	RED 630-640nm BLUE 415-425nm IR: 820-830nm YELLOW: 585-595nm	Red 620-633nm Blue 410-415nm IR 820-830nm / Yellow 585- 595nm
Effective irradiance	Adjustable 5 levels Red : 26-50 mW/cm^2 Blue : 9~41 mW/cm^2 Yellow: 12-20 mW/cm^2 IR: 11~28 mW/cm^2	Adjustable 4 levels Red: 19-47mW/cm^2 Blue: 25-40mW/cm^2 IR/Yellow: 29-61mW/cm^2
Operation interface	Continuous operation	Continuous operation

	Subject Device	Predicate Device
Operation mode	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471
Microprocessor control	Yes	Yes
Continuous/Pulsed Output	Continuous and Pulsed (up to 500 pulses per second)	Continuous

The proposed device, SMARTLUX MINI has been tested about electrical safety, EMC, and performance, and the software has been validated. Differences and Risks associated with that:

- The components of the subject device have similar composition as the components of the predicate device This difference does not influence the effectiveness and safety of product.
- The wavelengths and intensities emitted from subject device are similar to the wavelengths and intensities emitted by the predicate device. The predicate device emits light continuously during its treatment cycles. The SMARTLUX MINI also emits light continuously but it also has the option of emitting 50% duty cycle pulses at up to 500 times per second. This difference does not influence the effectiveness and safety of product.

8. Non-Clinical Test summary

The SMARTLUX MINI conforms with voluntary standards for electrical safety, electromagnetic compatibility. The following data were provided in support of the substantial equivalence determination:

1) Electrical Safety, Electromagnetic Compatibility and Performance:

The SMARTLUX MINI conforms with the electrical safety and electromagnetic compatibility requirements established by the standards.

Standards No.	Standards Organization	Standard Title	Version	Publication Year
ES60601-1	AAMI ANSI	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)	ES60601-1: 2005(R)2012 and A1:2012	2014
60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	60601-1-2 Edition 4.0 2014-02	2016
60601-2-57	IEC	Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use	60601-2-57 Edition 1.0 2011-01	2012
62471	IEC	Photobiological safety of lamps and lamp systems	IEC 62471 First edition 2006-07	2012

2) Software Validation

The SMARTLUX MINI contains MODERATE level of concern software. The software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance:

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).

9. Conclusion [21 CFR 807.92(b)(3)]

The SmartLux Mini light-emitting device that is the subject of this premarket notification uses similar technology and emits wavelengths and intensities of light that are similar to the predicate K192755. Testing of key performance characteristics demonstrates that the subject device can be used safely and effectively for the proposed indications for use. The Smartlux Mini light emitting device is considered to be substantially equivalent to the predicate device K192755.