October 25, 2024

Ulike Co., Ltd.
Blue Yang
Registration Director
2, Myeongdong, 6-gil, Jung-gu, Seoul, Korea
Seoul,
Korea, South

Re: K243030
Trade/Device Name: Diamond Air+ (UI04A, UI04B, UI04C, UI04M, UI04G, UI04W)
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: OHT
Dated: September 27, 2024
Received: September 27, 2024

Dear Blue Yang:

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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2024.10.25 20:07:43 -04'00'

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)*

K243030

Device Name

Diamond Air+ (UI04A, UI04B, UI04C, UI04M, UI04G, UI04W)

Indications for Use *(Describe)*

Diamond Air+ is an over-the-counter device intended for removal of unwanted body and/or facial hair. The device is also indicated for the permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

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.

510(k) Summary - K243030

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92. Prepared 10/24/2024.

1. Submitter's Information

Sponsor	
Company Name	Ulike Co., Ltd.
Address	2, Myeongdong, 6-gil, Jung-gu, Seoul, Korea
Contact Person	Ms. Blue Yang
Title	Regulatory Director
Email	blue@ulike.com

2. Subject Device Information

Trade Name	Diamond Air+ (UI04A, UI04B, UI04C, UI04M, UI04G, UI04W)
Classification Name	Laser Surgical Instruments for Use in General and Plastic Surgery
Review Panel	General & Plastic Surgery
Product Code	OHT
Regulation Class	2
Regulation Number	878.4810

3. Predicate Device Information

Predicate device I :

Predicate Device	I
Sponsor	Ulike Co., Ltd.
Device Name	Diamond Air+(UI04A, UI04B, UI04C)

510(k) Number	K221553
Product Code	OHT
Regulation Number	878.4810
Regulation Class	2

4. Device Description

Diamond Air+, Model: UI04A, UI04B, UI04C, UI04M, UI04G, UI04W is a light-based device for long-term hair removal. It is intended for the removal of unwanted hair and permanent reduction in hair regrowth. Ideal body areas include the underarms, bikini line, arms and legs. The device used the IPL technology with lower energy level, including 5 Levels of output energy. Intense Pulsed light technology can achieve long-term hair removal results at a fraction of the energy level used in other light -based hair removal equipment.

The size of the device is about 60*38*169.86mm (W x D x H). The device incorporates Intense Pulse Light (IPL) technology. The purpose of the light is to heat the root where the hair grows.

The device contains a Xenon Lamp and a skin proximity sensor to detect appropriate skin contact. If the Diamond Air+ is not properly applied to the treatment area (in full contact with the skin), the device cannot be triggered a pulse emitting.

5. Intended Use / Indications for Use

The Diamond Air+ (Model: UI04A, UI04B, UI04C,UI04M, UI04G, UI04W) is an over-the-counter device intended for removal of unwanted body and/or facial hair. The device is also indicated for the permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

9. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of the Diamond Air+, model: UI04A, UI04B, UI04C, UI04M, UI04G, UI04W are identical to the cited predicate. The sole difference between the subject and predicate devices are the colors of the device housing.

The Diamond Air+ relies on the same technology as both predicate device: Intense Pulsed Light (IPL). Their energy source is the same: Xenon Arc Flashlamp.

The safety and efficacy of IPL treatment for hair reduction are governed by the following parameters:

• Wavelength of the emitted light (spectrum): Defines the interaction with specific chromophores (the part of the molecule responsible for its color) such as melanin, hemoglobin and water. The Diamond Air+ and the predicate device utilize the same spectrum(550-1200nm).

• Fluence/flux – defines the energy per area (e.g. joules per cm^2) for the treatment. The Diamond Air+ and the predicate device deliver the same maximum energy (6 J/cm2).

Conclusion:

The subject device “Diamond Air+, Model: UI04A, UI04B, UI04C, UI04M, UI04G, UI04W” is substantial equivalent to the predicate device.