October 1, 2025

Shenzhen Ulike Smart Electronics Co., Ltd.
Yang Blue
Registration Director
810, Bldg 1,Xunmei Science & Technology Plaza,No.8 Keyuan Rd
Science Park Community, Yuehai Sub-District, Nanshan Dist
Shenzhen, Guangdong 518000
China

Re: K252804
Trade/Device Name: Ice Cooling IPL Hair Removal Device (UI20S BK, UI20S BS, UI20S DB, UI20S GP, UI20S GR, UI20S MP, UI20S PW, UI20S RE, UI20S WH, UI20WG;UI20 BK, UI20 BL, UI20 BR, UI20 BS, UI20 DB, UI20 GP, UI20 GR, UI20 MP, UI20 PN, UI20 PW, UI20 RE, UI20 WH; UI06 PN, UI06 PL, UI06 JL, UI06 BR, UI06 DB,UI06 PR, UI06 OG,UI06RD,UI06 WH, UI06 MG, UI06 OB, UI06 LY, UI06 IG; UI06S PR, UI06S PN, UI06S WH, UI06S PRU, UI06S PNU, UI06S WHU; UI04 MK, UI04 BN, UI04 BU, UI04 CB, UI04 GY, UI04 LG, UI04 DG, UI04 PL, UI04 PN, UI04 SD, UI04 SG, UI04 MG; UI04S PP, UI04S BU, UI04S WH, UI04S PN; MI01 LP, MI01 CB, MI01 GR, MI01 PP, MI01 RM, MI01 WG, MI01 WH, MI01 BK)
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 3, 2025
Received: September 3, 2025

Dear Yang Blue:

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: 2025.10.01 19:51:39 -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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K252804 |

Please provide the device trade name(s).

Ice Cooling IPL Hair Removal Device (UI20S BK, UI20S BS, UI20S DB, UI20S GP, UI20S GR, UI20S MP, UI20S PW, UI20S RE, UI20S WH, UI20WG；UI20 BK, UI20 BL, UI20 BR, UI20 BS, UI20 DB, UI20 GP, UI20 GR, UI20 MP, UI20 PN, UI20 PW, UI20 RE, UI20 WH; UI06 PN, UI06 PL, UI06 JL, UI06 BR, UI06 DB,UI06 PR, UI06 OG,UI06RD,UI06 WH, UI06 MG, UI06 OB, UI06 LY, UI06 IG; UI06S PR, UI06S PN, UI06S WH, UI06S PRU, UI06S PNU, UI06S WHU; UI04 MK, UI04 BN, UI04 BU, UI04 CB, UI04 GY, UI04 LG, UI04 DG, UI04 PL, UI04 PN, UI04 SD, UI04 SG, UI04 MG; UI04S PP, UI04S BU, UI04S WH, UI04S PN; MI01 LP, MI01 CB, MI01 GR, MI01 PP, MI01 RM, MI01 WG, MI01 WH, MI01 BK)

Please provide your Indications for Use below.

Ice Cooling IPL Hair Removal Device with sapphire treatment window is indicated for the removal of unwanted 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.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)