

October 1, 2025

Merchsource LLC  
% Candice Qiu  
Registration Specialist  
Feiying Drug & Medical Consulting Technical Service Group  
Rm 2401 Zhenye International Business Center, No. 3101-90  
Qianhai Road  
Shenzhen, Guangdong 518052  
China

Re: K252096  
Trade/Device Name: Light Therapy Decollete Mask (1019135)  
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: OHS  
Dated: June 20, 2025  
Received: July 3, 2025

Dear Candice Qiu:

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](mailto: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 19:26:19  
-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**

510(k) Number (if known)

K252096

Device Name

Light Therapy Decollete Mask (1019135)

Indications for Use (Describe)

It is an over-the-counter device that is intended for use in the treatment of wrinkles in the décolletage area.

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## 510(k) Summary - K252096

"510(k) Summary" as required by 21 CFR Part 807.92.  
April 2, 2025

### I. Submitter

MerchSource LLC  
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Shirley Luo  
Senior Compliance Manager  
Tel: 1 949 900 6598  
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### II. Device

Name of Device: LIGHT THERAPY DECOLLETE MASK  
Model(s): 1019135  
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology  
Regulatory Class: II  
Product Code: OHS, ISA  
Regulation Number: 21 CFR 878.4810

### III. Predicate Device and Reference Device

#### Predicate device:

| <u>Manufacturer</u>     | <u>Predicate Device</u> | <u>510(k) Number</u> | <u>Approval Date</u> |
|-------------------------|-------------------------|----------------------|----------------------|
| ISMART DEVELOPMENTS LTD | décoLITE                | K242382              | November 8, 2024     |

### IV. Device Description

The subject device LIGHT THERAPY DECOLLETE MASK is a home use wearable LED phototherapy device whose purpose is to produce an even and narrow-band of light for the treatment of cosmetic indications including facial wrinkles and acnes.

The subject device consists of a decollete mask body unit that contains light emitting diodes (LEDs), a controller, straps and USB-C charging cable. And the device is powered by built-in rechargeable lithium battery on the controller.

The LEDs generate 2 kinds of light which include Red light (wavelength  $630\text{nm} \pm 5\text{nm}$ ) and Infrared light (wavelength  $850\text{nm} \pm 5\text{nm}$ ). A controller is connect to the decollete mask body unit to control

the device, such as turn on/off the device. And the straps used for securing the décollete mask unit to the body part.

## V. Indications for Use

It is an over-the-counter device that is intended for use in the treatment of wrinkles in the décolletage area.

## VI. Comparison of Technological Characteristics With the Predicate Device

| Comparison Elements                 | Subject Device                                                                                                  | Predicate Device                                                                                                                         | Remark                            |
|-------------------------------------|-----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| 510(k) Number                       | Pending                                                                                                         | K242382                                                                                                                                  | /                                 |
| Trade name                          | LIGHT THERAPY DECOLLETE MASK(Model:1019135)                                                                     | décoLITE                                                                                                                                 | /                                 |
| Manufacturer                        | MerchSource LLC                                                                                                 | ISMART DEVELOPMENTS LTD                                                                                                                  | /                                 |
| Regulation number                   | 21 CFR 878.4810                                                                                                 | 21 CFR 878.4810                                                                                                                          | Same                              |
| Classification Name                 | Light Based Over The Counter Wrinkle Reduction(OHS)                                                             | Light Based Over The Counter Wrinkle Reduction(OHS)                                                                                      | Same                              |
| Product code                        | OHS, ISA                                                                                                        | OHS                                                                                                                                      | Same                              |
| Device classification               | Class II                                                                                                        | Class II                                                                                                                                 | Same                              |
| Indication for use/<br>Intended use | It is an over-the-counter device that is intended for use in the treatment of wrinkles in the décolletage area. | The décoLITE LED device is an over-the-counter device that is intended for the use in the treatment of wrinkles in the décolletage area. | Similar                           |
| Prescription or<br>OTC              | OTC                                                                                                             | OTC                                                                                                                                      | Same                              |
| Dimension                           | <b>LED Mask</b><br>342.6mm*235.5*mm*7.5mm<br><b>Controller</b><br>130.1mm*37mm*25.7mm                           | Not publicly available                                                                                                                   | Different<br><b><u>Note 1</u></b> |
| Power supply                        | Input: DC5V, 1A<br>Battery specifications:<br>Li-ion rechargeable battery 2000MAh<br>3.7V                       | Not publicly available                                                                                                                   | Different<br><b><u>Note 2</u></b> |
| Sterilization                       | Not applicable                                                                                                  | Not applicable                                                                                                                           | Same                              |
| Light source                        | Light Emitting Diodes                                                                                           | Light Emitting Diodes                                                                                                                    | Same                              |
| Location for use                    | Decollete area                                                                                                  | Decollete area                                                                                                                           | Same                              |

| Comparison Elements                       | Subject Device                                                                    | Predicate Device                                                                                     | Remark                   |
|-------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------------|
| 510(k) Number                             | Pending                                                                           | K242382                                                                                              | /                        |
| Wavelength                                | 630nm $\pm$ 5nm visible red light;<br>850nm $\pm$ 5nm Invisible red light         | Red: 630nm $\pm$ 10nm<br>NIR: 830nm $\pm$ 10nm                                                       | Similar<br><b>Note 3</b> |
| Irradiance<br>(mW/cm <sup>2</sup> )       | 30mW/cm <sup>2</sup>                                                              | 30mW/cm <sup>2</sup>                                                                                 | Same                     |
| Treatment time                            | 10 minutes                                                                        | 10 minutes                                                                                           | Similar                  |
| Compliance with<br>voluntary<br>standards | IEC 60601-1;<br>IEC 60601-1-2;<br>IEC 60601-1-11;<br>IEC 60601-2-83;<br>IEC 62471 | IEC 60601-1;<br>IEC 60601-1-2;<br>IEC 60601-1-11;<br>IEC 60601-2-83;<br>IEC 60601-2-57;<br>IEC 62471 | Same                     |
| Biocompatibility                          | ISO 10993-1<br>ISO 10993-5<br>ISO 10993-10<br>ISO 10993-23                        | Not publicly available                                                                               | /                        |

## VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

### **1) Biocompatibility Evaluation**

The biocompatibility evaluation for the body-contacting components of the Intense pulsed light device was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on September 4, 2020", as recognized by FDA. The following testing was performed to, and passed, including:

- ISO 10993-5:2009, Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021, Biological evaluation of medical devices –Part 10: Tests for skin sensitization

ISO 10993-23:2021, Biological evaluation of medical devices –Part 23: Tests for skin irritation

## **2) Electrical Safety and EMC**

Electrical safety and EMC testing was performed to, and passed, as per the following standards:

- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-2-83:2019 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

## **3) Eye Safety**

- IEC 62471:2006 Photobiological safety of lamps and lamp systems

## **4) Software Verification and Validation**

Software documentation consistent with *moderate level* of concern was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

## **5) Usability**

The product usability has been evaluated and verified according to the following FDA guidance

- Applying Human Factors and Usability Engineering to Medical Devices, issued on FEBRUARY 2016.

## **VIII. Conclusions**

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device LIGHT THERAPY DECOLLETE MASK is as safe, as effective, and performs as well as the legally marketed predicate device.