January 4, 2023

Jeisys Medical Inc
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, California 92612

Re: K223685
Trade/Device Name: SmoothCool HR System
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: December 7, 2022
Received: December 9, 2022

Dear Priscilla Chung:

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 -S

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)*

K223685

Device Name

SmoothCool HR System

Indications for Use *(Describe)*

The SmoothCool HR System is indicated for hair removal (permanent hair reduction).

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

(k223685)

Dec 30, 2022

## 1. Submitted by:

Jeisys Medical Inc
307, 308, 401, Daeryung Techno Town 8th, 96, Gamasan-ro, Geumcheon-Gu, Seoul, 08501, Republic of Korea

## 2. US Agent/ Official Correspondent:

Priscilla Chung

LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160
Irvine, CA 92612
Tel: 714.202.5789 Fax: 714.409.3357
Email: juhee.c@LKconsultingGroup.com

## 3. Device Name:

- Trade Name : SmoothCool HR System
- Classification : Class II
- Classification Name : Powered Laser Surgical Instrument
- Product Code : GEX
- Regulation Number : 21 CFR 878.4810
- Review Panel : General Hospital

## 4. Predicate Device:

- SmoothCool HR System (K213484) by Jeisys Medical Inc.

## 5 Device Description:

The SmoothCool HR System is an Intense Pulsed Light (IPL) system used hair removal (Permanent hair reduction) in the area of dermatology. The system consists of a console containing the power unit and control electronics with control and display panel including

software. Applicators/hand pieces are connected to the system in order to generate light energy for treatment in the waveband 420-950 nm. Four different hand pieces are attached with the system.

## 6 Indications for Use Statement

The SmoothCool HR System is indicated for hair removal (permanent hair reduction).

## 7 Substantial Equivalence Discussion:

### 7.1.Comparison Chart

| Proprietary | **Subject Device** | **Primary Predicate Device** |
|---|---|---|
| Manufacturer | Jeisys Medical Inc. | Jeisys Medical Inc. |
| Device Name | SmoothCool HR System | SmoothCool HR System |
| 510(k) Number | k223685 | k213484 |
| Device Classification Name | Laser surgical instrument for use in general and plastic surgery and in dermatology | Laser surgical instrument for use in general and plastic surgery and in dermatology |
| Product Code | GEX | GEX |
| Regulation Number | 878.4810 | 878.4810 |
| Intended Use | The SmoothCool HR System is indicated for hair removal (permanent hair reduction). | The SmoothCool HR System is indicated for hair removal (permanent hair reduction). |
| Components | ▪ Main Console<br><br>▪ Hand Pieces:<br>420nm(S) Handpiece<br>560nm(S) Handpiece<br>700nm(S) Handpiece<br>700nm(L) Handpiece<br><br>▪ Filters<br>800, 700, 640, 590, 560, 545(V), 530, 530(D), 530(s), 500, 420(s)nm<br><br>▪ Eyes Protector<br><br>▪ Power Cord | ▪ Main Console<br><br>▪ Hand Pieces:<br>420nm(S) Handpiece<br>560nm(S) Handpiece<br>700nm(S) Handpiece<br>700nm(L) Handpiece<br><br>▪ Filters<br>800, 700, 560, 530, 530(s), 420(s)nm<br><br>▪ Eyes Protector<br><br>▪ Power Cord |
| Power Output | Up to 65 J/cm2 | Up to 65 J/cm2 |
| Sterile | No | No |

### 7.2. Substantial Equivalence Discussion

The indications for use and the technological characteristics of the subject device are the same as the predicate device, the unmodified device (k213484). The modification is adding more filters. The power output and also the range of the filter remained the same. We also performed risk analysis and verification/validation tests per modification, and the test results support that the modifications do not raise a question in safety and performance.

## 8. Technological Characteristics:

The SmoothCool HR System and the predicate devices in the market have the substantially equivalent technological characteristics. Risks associated with the changes were identified and appropriate design controls implemented to mitigate the risks.
To validate the control of the risks, the following tests were performed.

| No | Test |
|---|---|
| 1 | Energy Output Test |
| 2 | Button Operation Test |

## 9. Conclusion:

Based on the information provided in this special 510(k), the SmoothCool HR System is substantially equivalent to the predicate devices.