April 20, 2022

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

Re: K213484
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: October 18, 2021
Received: October 29, 2021

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,

Purva Pandya
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)*

K213484

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.

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510(K) SUMMARY

(K213484)

Apr 20, 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

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18881 Von Karman Ave STE 160
Irvine, CA 92612
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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 (K082911) by Jeisys Medical Inc.
- Stellar M22 for Intense Pulsed Light (IPL) and Laser system (K193500) by Lumenis Ltd.

5 Device Description:

SmoothCool HR System is an Intense Pulsed Light (IPL) system used for 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. Four different hand pieces are offered with the system.

6 Indications for Use Statement

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

7 Substantial Equivalence Discussion:

Proprietary	**Subject Device**	**Primary Predicate Device**	**Reference Device**
Manufacturer	Jeisys Medical Inc.	Jeisys Medical Inc.	Lumenis Ltd.
Device Name	SmoothCool	SmoothCool	Stellar M22 for Intense Pulsed Light (IPL) and Laser system
510(k) Number	-	K082911	K193500
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	Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code	GEX	GEX	GEX
Regulation Number	878.4810	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).	The subject Stellar M22 has connection capability with the following available treatment handpieces, for multi-application treatment options. All handpieces are designed for aesthetic and dermatological skin procedure applications, as follows: □ **The Intense Pulsed Light (IPL) handpiece with a spectrum of 400-1200 nm (with 9 different filters) is indicated for:** o Benign epidermal lesions, including dyschromia, hyperpigmentation, melasma, and ephelides (freckles) o Cutaneous lesions, including warts, scars and striae o Benign cutaneous vascular

			lesions, including port wine stains, hemoangiomas, facial,truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations o Removal of unwanted hair and to effect stable long term, or permanent* hair reduction in skin types I-V through selective targeting of melanin in hair follicles o Mild to moderate inflammatory Acne (Acne vulgaris) **The Nd:YAG Laser handpiece with a wavelength of 1064 nm (Multi-Spot Nd:YAG) is indicated for:** o The coagulation and hemostasis of vascular lesions and soft tissue, including the treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1-4.0 mm. diameter) of the leg o The removal of unwanted hair and to effect table long term, or permanent* hair reduction in skin types I-V through selective targeting of melanin in hair follicles o The non-ablative treatment of facial wrinkles **ResurFX module and handpiece, with wavelength of 1565 nm, is indicated for:** o Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue **The Q-Switched Nd:YAG Laser Handpiece with a wavelength of 1064 nm is indicated for:** o Removal of dark tattoos o Treatment of pigmented lesions *Note Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after completion of treatment regime.

Components	▪ Main Console ▪ Hand Pieces: 420nm(S) Handpiece 560nm(S) Handpiece 700nm(S) Handpiece 700nm(L) Handpiece ▪ Filters 800, 700, 560, 530, 420nm ▪ Eyes Protector ▪ Power Cord	▪ Main Console ▪ Hand Pieces: 560nm(S) Handpiece 700nm(S) Handpiece 700nm(L) Handpiece ▪ Filters 700, 560nm ▪ Eyes Protector ▪ Power Cord	▪ Main Console ▪ IPL Handpiece 400-1200 nm ▪ ResurFX Handpiece 1565 nm ▪ Multi-Spot Nd:YAG Handpiece 1064 nm ▪ Q-Switched Nd:YAG Handpiece 1064 nm
Power Output	Up to 65 J/cm2	Up to 65 J/cm2	▪ IPL Handpiece Up to 56 J/cm2 ▪ Multi-Spot Nd:YAG Handpiece 10~225 J/cm2 ▪ Q-Switched Nd:YAG Handpiece 0.9~14 J/cm2
Software	Software Validation	Software Validation	Software Validation
Sterile	No	No	No

The indications for use and the technological characteristics of the subject device is the same as the predicate device, the unmodified device (K082911). Modifications are the addition of handpieces and filters. We identified a reference device which has the same indications for use (hair removal) and encompasses the wavelength range of the subject device.
We performed risk analysis and verification/validation tests per modifications, 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	Standard
1	Energy Output Test	-
2	Electrical Safety and EMC	EN 60601-1 EN 60601-1-2 EN 60601-2-22

9. Conclusion:

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