January 6, 2026

EL Global Trade Ltd
Sivan Fishman
RA/QA Manager
Gibore Israel 13
Netanya, 42407
Israel

Re: K250341
Trade/Device Name: Sensilift Pro (ST300XXYYZZZ)
Regulation Number: 21 CFR 878.4420
Regulation Name: Electrosurgical Device For Over-The-Counter Aesthetic Use
Regulatory Class: Class II
Product Code: PAY
Dated: January 20, 2025
Received: February 6, 2025

Dear Sivan Fishman:

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.01.06 14:17:15 -05'00'

Colin K. Chen, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250341

Device Name

Sensilift Pro (ST300XXYYZZZ)

Indications for Use *(Describe)*

The sensilift Pro is an over-the-counter home use device intended for non-invasive treatment of mild to moderate facial wrinkles for adults who have Fitzpatrick Skin Types I-IV.

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
EL Global Trade Ltd. For Sensilift Pro

K250341

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1. DATE PREPARED: January 5th, 2026

2. 510(K) OWNER NAME

EL Global Trade Ltd.
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Contact person name:
Sivan Fishman, RA/QA Manager
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3. DEVICE NAME

Common/Usual Name: OTC device for skin tightening based on RF

Proprietary/Trade Name: Sensilift Pro

Model Name: ST300

Classification: EL Global Trade Ltd.'s Sensilift Pro device has been classified as a **Class II** device under the following classification names:

Classification Name	Product Code	Regulation Number	Panel
Electrosurgical device for over-the-counter (OTC) aesthetic use	PAY	878.4420	General and Plastic Surgery

4. PREDICATE DEVICES

EL Global Trade Ltd.'s Sensilift Pro device is substantially equivalent to the following Predicate Devices:

4.1. Sensilift device

Cleared under 510(k) number **K170499** on June 15th, 2017.

4.2. Pollogen STOP U Model UXV device

Cleared under 510(k) number **K220322** on May 4th, 2023.

5. DEVICE DESCRIPTION

The Sensilift Pro device is an OTC, home-use hand-held device generating radiofrequency (RF) energy that is emitted into the skin. RF energy heats the tissue to improve the appearance of wrinkles and rhytides. It is a non-invasive, non-ablative device consisting of:

- User Interface
- Programmable logic controller (PLC, microcontroller) embedded in PCBA
- RF power module
- Power Supply
- RF electrodes

The PLC (on the PCBA) is a specially configured software that, combined with hardware circuits, provides the operational and safety functions of the system. The RF power module provides RF energy to the active tip electrodes, producing a signal of 1MHz frequency (power limited by hardware). This device is supplied non-sterile.

Technical specifications:

- Maximal power output: 6 ±1 Watt.
- Frequency: 1±0.05 MHz
- Maximal temperature allowed: 40 ± 0.5^0C.

6. INTENDED USE/ INDICATIONS FOR US

The *Sensilift Pro device* is an over-the-counter home-use device intended for the non-invasive treatment of mild to moderate facial wrinkles for adults with Fitzpatrick skin types I-IV.

7. NON-CLINICAL (BENCH) PERFORMANCE DATA

The following performance data (bench tests) were provided in support of the performance, safety, and efficacy of the *Sensilift Pro* device as well as the substantial equivalence determination.

Safety Bench Tests and Verification & Validation (V&V) Summary

Bench testing was conducted per the IEC standard 60601 family to demonstrate that the Sensilift Pro device performs as expected under anticipated conditions of use. These tests included safety performance verification (electrical and mechanical) according to IEC 60601-1, essential requirements according to IEC 60601-1-2, and particular requirements for home use medical devices per IEC60601- 1-11.

In addition, the following bench testing was conducted (among others) to demonstrate the device performance characteristics as part of the V&V:

- **Overheating safety**. The two redundant thermistors embedded in the device constantly measure the skin temperature and constantly alter the power emitted to maintain the temperature constant within the target treatment temperature range (maximal temperature of 40 ± 0.50C). This temperature was determined to be acceptable based on published information from the National Institute for Standard and Technology (http://www.nist.gov/fire/fire_behavior.cfm) which states that human skin begins to feel pain at 44°C and may start to develop skin burns at 48°C.

- **Power accuracy**. The device was validated on a 200 Ω load, which is appropriate as the reference of the average load of the user. The measured total power was within the error margin, indicating that the device met the acceptance criteria.

- **Parameter validation**. The device was tested for its varied parameters, including radio frequency, pulse cycle, wave form and pulse duration. All results were within the acceptance criteria.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Sensilift Pro device. The device complies with:

- IEC 60601-1:2005/EN 60601-1:2006, General safety standard: safety requirements for medical electrical systems.
- IEC 60601-1-2:2014/EN 60601-1-2:2015, Medical electrical equipment Part 1-2 - General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
- IEC 60601-1-11:2015, Medical electrical equipment Part 1-11 – Requirements for the medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601-2-2: 2017, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff,

"Guidance for the Content of Premarket Submissions for Device Software Functions." The document level for this software was considered "Basic".

Cybersecurity Information

Due to the inclusion of a Bluetooth connectivity component, cybersecurity documentation was included in the submission as recommended by FDA's Guidance for Industry and FDA Staff, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions". The documentation included Threat Modeling, Cybersecurity Risk Assessment, Vulnerability Report, Penetration Testing, SBOM, Architecture Views, Security Assessment of Unresolved Anomalies, Cybersecurity Metrics and Cybersecurity Controls, as well as Cybersecurity Management Plan and Cybersecurity Risk Management Report.

The information gathered in the documents above, and as summarized in the Cybersecurity Risk Management Report, demonstrates that the overall cybersecurity risk of the Sensilift Pro (ST300) system is LOW, and the system is considered to meet FDA premarket cybersecurity expectations for medical devices at the time of submission.

Human Factors Validation Testing

The human factors and usability validation of the Sensilift Pro device is based on:

1. IEC 60601-1-6:2010 test report
2. A self-selection and human factors validation study

A Self-Selection and Human Factors validation study was performed to demonstrate that users can safely and effectively self-select, prepare, and perform treatment with the Sensilift Pro device.

The Self-Selection study proved the self-selection of the users, reaching El Global's

goal. 15 subjects who successfully self-selected themselves as eligible for treatment with the device, performed treatment with the Sensilift Pro device using the device labeling and IFU. The users participating reached a validation rate of 100% success rate for all critical tests, with no critical issues raised during use. These results demonstrated that the design of the Sensilift Pro device is safe for use by the intended lay users.

8. PERFORMANCE TESTING - ANIMAL

No animal testing was performed with the subject device.

9. CLEANING, STERILIZATION, SHELF LIFE AND BIOCOMPATIBILITY

The Sensilift Pro device is a non-sterile, reusable device, intended for a single user. The device cleaning instructions are based on the cleaning instructions of the predicate device due to the fact that both devices are made from the same materials and used similarly.

The shelf-life expectancy of the device is 5 years, similarly to the predicate device.

The biocompatibility evaluation for the *Sensilift Pro* device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" September 4, 2020, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.
EL Global has categorized its *Sensilift Pro* device as a: *"surface medical devices that are in contact with intact skin for limited contact duration (≤24 hours)",* in accordance with Table A.1 of ISO 10993-1:2018.

In the case of a device with such a classification, the prerequisite information for

the risk assessment is the physical and/or chemical information (in accordance with ISO 10993-18). Additional endpoints required for this classification in case of missing or insufficient information are Cytotoxicity, Sensitization and Irritation.

Components of the Sensilift Pro device were tested in accordance with REACH and RoHS standards in order to confirm that no dangerous or toxic materials are present in the device composition. Additionally, the materials used in the manufacture of the device are materials commonly used in the medical device industry. These materials are also used in the manufacturing process of El Global Trade Ltd.'s sensiLift device, for which Cytotoxicity, Irritation and Sensitization tests (in accordance with ISO 10993:5 and ISO 10993:10) were performed.

10. CLINICAL PERFORMANCE DATA

No clinical testing was performed with the subject device, as it is substantially equivalent to the predicate device, and thus requires no additional clinical data to prove its safety and efficacy.

11. SUBSTANTIAL EQUIVALENCE

The indications for use and technological characteristics of the Sensilift Pro device are substantially equivalent to the indications for use and technological characteristics of the predicate device, as can be seen in the technology comparison table below.

The design and components of both devices (i.e., power supply, RF generator, and controller) are similar. The performance specifications of the Sensilift Pro (i.e., RF frequency and electrical power) are substantially equivalent to those of the predicate device. The safety features and compliance with safety standards of both are similar. The body contact materials are similar. The minor differences in the technological characteristics do not raise new safety or effectiveness concerns and are demonstrated to be substantially equivalent through relevant performance tests. Furthermore, the Sensilift Pro device has qualified with varied performance tests,

including software validation testing, electrical and mechanical safety testing according to IEC 60601-1, electromagnetic compatibility testing according to IEC 60601-1-2, compatibility as medical electrical equipment for home healthcare environment according to 60601-1-11, and high frequency of surgical equipment according to IEC 60601-2-2. The performance tests demonstrated that the device specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Table 1. Substantial Equivalence of EL Global's Sensilift Pro with Predicate Devices.

Feature	EL Global *Sensilift Pro* *New Device*	EL Global Sensilift [K170499] Predicate Device 1	Pollogen STOP U Model UXV [K220322] Predicate Device 2	Characteristics comparison (similarity)
	Regulatory information			
Device Class	Class II	Class II	Class II	Identical
Classification Panel	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery	Identical
Product Code	PAY	PAY	PAY	Identical
Regulation Number	21 CFR 878.4420	21 CFR 878.4420	21 CFR 878.4420	Identical
Device	Over-The-Counter Radiofrequency Coagulation Device for Wrinkle Reduction	Over-The-Counter Radiofrequency Coagulation Device for Wrinkle Reduction	Over-The-Counter Radiofrequency Coagulation Device for Wrinkle Reduction	Identical
Regulation Description	Electrosurgical device for over-the-counter aesthetic use	Electrosurgical device for over-the-counter aesthetic use	Electrosurgical device for over-the-counter aesthetic use	Identical
Intended Use	The Sensilift Pro™ is an over-the-counter home-use device intended for non-invasive treatment of mild to moderate facial wrinkles for adult users who have Fitzpatrick Skin Types I-IV.	The Sensilift™ is an over-the-counter home-use device intended for non-invasive treatment of mild to moderate facial wrinkles for adult women who have Fitzpatrick Skin Types I-IV.	The Stop U Model UXV Skin RF is an over-the-counter home use device intended for non-invasive treatment of mild to moderate facial wrinkles for adult users who have Fitzpatrick Skin Types I-IV.	Similar, Identical to predicate 2
	Device Characteristics			
Mode of Operation	The device is a home-use hand-held device	The device is a home-use hand-held device generating RF	The device is a home-use hand-held device generating RF	Identical

Feature	EL Global *Sensilift Pro* *New Device*	EL Global Sensilift [K170499] Predicate Device 1	Pollogen STOP U Model UXV [K220322] Predicate Device 2	Characteristics comparison (similarity)
	generating RF energy that is emitted into the skin. RF energy heats the tissue to improve the appearance of wrinkles and rhytides. It is a non-invasive and non-ablating device.	energy that is emitted into the skin. RF energy heats the tissue to improve the appearance of wrinkles and rhytides. It is a non-invasive and non-ablating device.	energy that is emitted into the skin. RF energy heats the tissue to improve the appearance of wrinkles and rhytides. It is a non-invasive and non-ablating device.	
Energy Source	1 MHz RF (Bi-polar)	1 MHz RF (Bi-polar)	1 MHz RF (Bi-polar)	Identical
Number of Electrodes	2 electrodes (1 pair of Bi-polar electrodes).	2 electrodes (1 pair of Bi-polar electrodes).	4 round electrodes (2 pairs of Bi-polar electrodes)	Identical to predicate 1
Treatment Areas	Face: lower cheek (perioral), upper cheek (periorbital), and under the chin.	Face: lower cheek (perioral), upper cheek (period) (periorbital), and under the chin.	Face: lower cheek (perioral), upper cheek (periorbital) and under the chin.	Identical
Treatment Regimen	5 minutes per area, once a week, for 8 consecutive weeks	5 minutes per area, once a week, for 8 consecutive weeks	5 minutes per area, once a week, for 8 consecutive weeks.	Identical
Intended Population	Healthy adults (Fitzpatrick skin types I-IV) who desire to reduce facial wrinkles.	Healthy adult women (Fitzpatrick skin types I-IV) who desire to reduce facial wrinkles.	Healthy adults (Fitzpatrick skin types I-IV) who desire to reduce facial wrinkles.	Identical to predicate 2
Use Environment	Home Use, self-operation by an unprofessional user.	Home Use, self-operation by an unprofessional user.	Home Use, self-operation by an unprofessional user.	Identical
	Device Features			
Handpiece Dimensions, (LXHXW) [mm^3]	190 X 55 X 51	173 X 56.8 X 53	134 X 51 X 32	See note 1

Feature	**EL Global** ***Sensilift Pro*** *New Device*	**EL Global Sensilift** [K170499] Predicate Device 1	**Pollogen STOP U Model UXV** [K220322] Predicate Device 2	**Characteristics comparison (similarity)**
Weight [gr]	205	122	85	See note 1
Electrode Treatment Area [mm^2]	176	176	100	Identical to predicate 1
Body Contact Materials	ABS plastic shell. Chrome coated electrodes.	ABS plastic shell. Chrome coated electrodes.	ABS plastic shell. Chrome coated electrodes.	Identical
User Interface	• 1 LED: device status indicator (yellow green) • 1 LED panel (energy level, green) • 1 LED panel (speed level, green) • 1 LED: battery status indicator (red-green-no light)	• 1 LED: device status indicator (yellow green) • 1 LED panel (energy level, green) • 1 LED panel (speed level, green)	• 1 LED: device status indicator (orange,) • 2 LED panel (energy level, green)	Similar, see note 2
User Selectable Energy Levels	3 energy levels deliver: • Level 3 – 6 W • Level 2 – 5 W • Level 1 – 3.5 W	3 energy levels deliver: • Level 3 – 6.5W • Level 2 – 5W • Level 1 – 3.5W	2 energy levels deliver: • Level 2 – 5.7 W • Level1– 3.5W	Similar, see note 3.
RF Energy Emission Indicator	Yes (Temperature sensor)	Yes (Temperature sensor)	Yes (Temperature sensor)	Identical
External Power Supply	100-240 V, 50-60 Hz 12 V, 1.8 A	100-240 V, 50-60 Hz 9 V, 1.5 A	100-240 V 50-60 Hz 8 V, 1.5 A	Similar. See note 4
	Safety standards			
Safety/EMC	**IEC 60601-1:2024/EN 60601-**	**IEC 60601-1:2024/EN 60601-1:2006+A2:2021**,	**IEC 60601-1:2024/EN 60601-1:2006+A2:2021**,	Identical. Sensilift Pro has the same

Feature	EL Global *Sensilift Pro* *New Device*	EL Global Sensilift [K170499] Predicate Device 1	Pollogen STOP U Model UXV [K220322] Predicate Device 2	Characteristics comparison (similarity)
	1:2006+A2:2021, General safety standard: safety requirements for medical electrical systems. **IEC 60601-1-2:2014**, Medical electrical equipment Part 1-2 - General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests. **IEC 60601-1-11: 2015+A1:2020**, Medical electrical equipment Part 1-11 – Requirements for the medical electrical equipment and medical electrical systems used in the home healthcare environment. IEC 60601-2-2: 2017, Medical electrical equipment - Part	General safety standard: safety requirements for medical electrical systems. **IEC 60601-1-2:2014**, Medical electrical equipment Part 1-2 - General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility – Requirements And Tests. **IEC 60601-1-11: 2015+AMD1:2020**, Medical electrical equipment Part 1-11 – Requirements for the medical electrical equipment and medical electrical systems used in the home healthcare environment. IEC 60601-2-2: 2017, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high	General safety standard: safety requirements for medical electrical systems. **IEC 60601-1-2:2014**, Medical electrical equipment Part 1-2 - General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests. **IEC 60601-1-11: 2015+AMD1:2020**, Medical electrical equipment Part 1-11 – Requirements for the medical electrical equipment and medical electrical systems used in the home healthcare environment. **IEC 60601-2-2: 2017**, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high	safety/EMC certifications as the predicate device.

Feature	EL Global *Sensilift Pro* *New Device*	EL Global Sensilift [K170499] Predicate Device 1	Pollogen STOP U Model UXV [K220322] Predicate Device 2	Characteristics comparison (similarity)
	2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.	frequency surgical accessories.	frequency surgical accessories.	
Biocompatibility	All parts that are in contact with the user comply with the requirements for **ISO 10993-1: 2018,** Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. **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.	All parts that are in contact with the user comply with the requirements for **ISO 10993-1: 2009,** Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. **ISO 10993-5: 2009,** Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity. **ISO 10993-10: 2010,** Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.	All parts that are in contact with the user comply with the requirements for **ISO 10993-1: 2018,** Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. **ISO 10993-5: 2009,** Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity. **ISO 10993-10: 2010,** Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.	Identical

Feature	EL Global *Sensilift Pro* *New Device*	EL Global Sensilift [K170499] Predicate Device 1	Pollogen STOP U Model UXV [K220322] Predicate Device 2	Characteristics comparison (similarity)
	ISO 10993-23: 2021, Biological evaluation of medical devices - Part 23: Tests for irritation.			
Software	The software was verified and validated according to the FDA guidance. Moderate Level of Concern.	The software was verified and validated according to the FDA guidance. Moderate Level of Concern.	The software was verified and validated according to the FDA guidance. Moderate Level of Concern.	Identical

Note No. 1. Device Size and Weight.

The size and weight of the hand-held device are basic unit characteristics with no effect on the intended use, the safety, nor the efficacy of the device. The Sensilift Pro device was designed to allow an ergonomic and fatigue-free grip during several minutes of treatment by the naïve user. The additional components (battery) result in increased dimensions and weight.

Note No. 2. User Interface and Safety Mechanism.

Both user interface elements and the safety mechanisms of the Sensilift Pro device were designed to meet the needs of the naïve user at home.

The Sensilift Pro includes one more LED compared to the predicate device, related to the status of the device battery (Sensilift Pro is a cordless device, while Sensilift requires a power supply connection during use). The device being rechargeable does not affect the safety and effectiveness of the treatment. In the other hand, STOP U device has static electrodes, therefore, it has only two LED's: One for RF and the second for status.

Note No. 3. Energy Levels.

The energy levels in Sensilift Pro are the same as Sensilift and STOP U devices. While the STOP U device has only two levels, which are similar to the minimum and maximum energy in the subject device. The only difference

is in the highest energy level, the power of which is 6.5W for Sensilift, 5.7W for STOP U, as opposed to 6W for Sensilift Pro. Due to the tolerance of the power, the difference in the highest energy in the three devices is negligible. Thus, Sensilift Pro is as safe and effective as Sensilift and STOP U.

Note No. 4. External Power Supply.

The power supply specifications do not affect the safety and efficacy of the device.

12. CONCLUSIONS

Due to these identical clauses and high similarities, the Sensilift Pro device is as safe and as effective as the predicate device, since they share the same intended use, technological characteristics, features, specifications, materials, and anatomical site for use. The differences between the Sensilift Pro device and the predicate device do not raise new safety or effectiveness issues or questions, as detailed above. Based on performance testing and comparison to predicate devices, the Sensilift Pro device is as safe and effective and substantially equivalent to the predicate device.