DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 15, 2017

El Global Trade Ltd
Dr. Yael Liebes-Peer
RA/ QA Manager
8 Tzoran St, P.O. Box 8242
Netanya, 4250608 Israel

Re: K170499
Trade/Device Name: sensiLift
Regulation Number: 21 CFR 878.4420
Regulation Name: Electrosurgical Device for Over-The-Counter Aesthetic Use.
Regulatory Class: Class II
Product Code: PAY
Dated: May 7, 2017
Received: May 12, 2017

Dear Dr. Yael Liebes-Peer:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170499

Device Name
sensiLift

Indications for Use *(Describe)*

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.

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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sensiLift – K170499/ S001	RD- 11118 B2

DATE PREPARED: APRIL 24TH, 2016

1. 510(K) OWNER NAME

EL Global Trade Ltd.

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Phone: +972-9-7889069, Fax: +972-9-7734831.

Contact person name: Dr. Yael Liebes-Peer, RA/ QA Manager

Phone: +972-9-7889069, Fax: +972-9-7734831, E mail: Yael@sensica.com

2. DEVICE NAME

Common/ Usual Name: OTC device for treatment of facial wrinkles based on RF

Proprietary/Trade name: *sensiLift*

Classification: EL Global Trade Ltd.'s *sensiLift* device has been classified as **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

3. PREDICATE DEVICES

EL Global Trade Ltd.'s *sensiLift* device is substantially equivalent to the following Predicate Device:

3.1 EndyMed Medical Ltd.'s NEWA device,

cleared under De-Novo number **DEN150005** at Dec 18th, 2016.

4. DEVICE DESCRIPTION

The sensiLift is an OTC, home use hand held device generating pulses of radiofrequency (RF) energy that are emitted into the skin. RF energy heats the

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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 user interface allows the selection of heating level: high, medium low or off, conjugated to movement speed level of the electrodes (also adjusted by the user): high or low. The PLC (on the PCBA) is a specially configured software that, combined with hardware circuits, provides the operational and safety function of the system. The RF power module provides RF energy to the active tip electrodes, producing a sinusoidal signal of 1MHz frequency (power limited by hardware). This device is supplied non-sterile.

Technical specifications:

- Maximal power output: 9±1 Watt.
- Skin level power: 3.5±1, 5±1 and 6.5±1 Watt (energy levels 1-3).
- Frequency: 1 MHz.
- Maximal temperature allowed: 40^0C.

5. INTENDED USE/ INDICATIONS FOR USE

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.

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6. NON-CLINICAL (BENCH) PERFORMANCE DATA

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

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

Bench testing was conducted per IEC standard 60601family to demonstrate that the *sensiLift* device performs as expected under anticipated conditions of use. This testing 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 device 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:

- Over-heating safety. The two redundant thermistors embedded in the device constantly measure the skin temperature and deactivate RF delivery when temperature exceeds 40^0C. 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 state 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 for the different power levels 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.

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- 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* device. The device complies with:

- IEC 60601-1:2005/EN 60601-1:2006, General safety standard: safety requirements for medical electrical systems.
- IEC 60601-1-2:2007, IEC 60601-1-2:2009, Medical electrical equipment Part 1-2 - General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
- IEC 60601-1-11:2010, 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: 2009, 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 Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern because inadvertent software errors could result in skin burns to the user.

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Human Factors Validation Testing

A human Factors Validation Testing was done to evaluate the HFE/ UE concerns, including label comprehension/ self-selection and usability/ user interface studies (one arm, simulated use and summative evaluation). In both studies, participants had received the labeling materials of the device, and given enough time to read it according to their own wish.

Labeling Comprehension/ Self Selection Study was aimed at demonstrating potential user comprehension of the device labeling (mainly the outer package) in order to decide if device use is appropriate for her. It had included three main questions regarding the intended use of the device, treatment areas and possibility to usse the device according to the contraindication, with correct answers: „Yes“ or „No“, explenation and further validation by the moderator. A total of 43 participants, 2 men and 41 women, from age 18 to 65 years old (45 ± 13 years old) were enrolled to this study. Participants had different educational levels, as obtained by REALM testing with 20% below 9th grade level. All participants had met the inclusion/ exclusion criteria and signed ICF. 100% of the participants had reported correct answers, as further validated by the moderator (κ=1).

Usability/ User Interface Study was aimed at demonstrating the OTC user can correctly use the device, based on the labeling material for the intended aesthetic puspose. The study was focused on four use scenarios including 22 relevant tasks: “preparing and knowing the device” (7 tasks), “self-preparation” (4 tasks), “device usage” (7 tasks) and “after usage” (3 tasks). None of the participants had required assistance from the moderator while performing the tasks. Altogether, all tasks were completed by 100% of the participants, and the success rate (pass criteria) was 100% per each task scenario.

In addition, the vast majority of the participants (14 out of 20) had additionally commented that the device usage is easy and clear and they are curios and would

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be interested in using the device. Some participants (7 out of 20) had additionally commented (though succeeded in operation) regarding the comfort of using the buttons. Only few (4 out of 20 participants) were concerned about other elements of the device.

Furthermore, when participants were asked regarding their user experience and satisfaction after the usability and user interface study, high satisfaction was obtained, with an average result was 1.66 ± 0.25, using a 1-5 discrete scale (when 1 represent best and 5 worst).

These two demonstrates that the intended OTC users can understand the package labeling, correctly choose the device and use it for the indicated aesthetic use, based solely on reading the lableling materials.

7. PERFORMANCE TESTING - ANIMAL

No animal testing was performed with the subject device

8. CLEANING, STERILIZATION, SHELF LIFE AND BIOCOMPATIBILITY

The *sensiLift* 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* 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,'" May 1, 1995, and International Standard ISO 10993-1

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"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* device as: *"Surface device, Skin Contact* for *limited contact duration",* with contact duration of less than 24h ("A", up to 24 hours). Therefore, the battery of testing included the following tests: cytotoxicity, sensitization and irritation tests. The body contact materials are biocompatible per:

- 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.

The sensiLift device is made of similar materials that come into contact with user's body as already cleared for the predicate device (DEN150005) and for the auxiliary sensiLight mini device (K140527 and K161089).

9. CLINICAL PERFORMANCE DATA

The *sensiLift* safety and efficacy, when used at a home setting, for non-invasive treatment of mild to moderate facial wrinkles of adult women with Fitzpatrick Skin Types I-IV was examined in an open label, prospective, interventional single arm study clinical study.

40 females between the ages 40-64, fulfilling the inclusion/ exclusion criteria, were enrolled to the study by the Principle Investigator (PI) and treated 2-3 treatment regions (perioral, periorbital and chin regions), according to their preference and the physician approval. 35 participants (total of 87 treatment areas) had completed 8 treatments according to the instructions for use and appeared to the 3 months after treatments last follow-up (FU2). The wrinkles appearance was assessed using the Fitzpatrick Wrinkles Severity Scale and improvement was defined as decrease of at least one score in the Scale. This assessment was conducted by 3 independent physicians (beside the PI, 3 board certified

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dermatologists or plastic surgeons) at the end of the active treatment regimen (T8), 1 and 3 months after the last treatment (follow-up regimen FU1 and FU2, respectively).

No adverse events occurred during and after the study, meaning that the success criteria for primary safety endpoint have been met. As for effectiveness, after the completion of the active treatment regimen, 89%, 95% and 95% of the study participants (as assessed by 3 reviewers, respectively) have shown improvement in overall facial wrinkles appearance. Similarly, improvement was observed at the end of the Follow-up regimen, 3 months after the last treatment, for 97%, 100% and 100% of the participant by the three evaluators. In addition, all the participants were highly satisfied with the device at the end of the study. 89% reported on improvement in their skin's appearance.

These results demonstrate that the device performs as intended under anticipated conditions of use (home environment) to achieve the intended aesthetic results.

10. SUBSTANTIAL EQUIVALENCE

The indications for use and technological characteristics of the sensiLift device are substantially equivalent to the indications for use and technological characteristics of the predicate device. A detailed comparison between the sensiLift by EL Global LTD. proposed device and the predicate device is presented at Table 1 below, including the similarities and differences and the related conclusion.

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Table 1. Substantial Equivalence of EL Global's sensiLift with Predicate Device.

Feature	EL Global *sensiLift* *New Device*	EndyMed *Newa™* [DEN150005] *Predicate Device*	Characteristics comparison (similarity)
Regulatory information			
Device Class	Class II	Class II	Identical
Classification Panel	General and Plastic Surgery	General and Plastic Surgery	Identical
Product code	PAY	PAY	Identical
Regulation number	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	Identical
Regulation description	Electrosurgical device for over-the-counter aesthetic use	Electrosurgical device for over-the-counter aesthetic use	Identical
Intended use	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 EndyMed Newa™ 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.	Identical
Device characteristics			
Mode of Operation	The device a home-use hand-held device generating pulses RF energy that emitted into the skin. RF energy heats the tissue to improve the appearance of wrinkles and rhytides. It is non-invasive and non-ablating device.	The device is a home-use hand-held device generating pulses of RF energy that emitted into the skin. RF energy heats the tissue to improve the appearance of wrinkles and rhytides. It is non-invasive and non-ablating device.	Identical
Energy Source	1 MHz RF (Bi-polar)	1 MHz RF (Bi-polar)	Identical
Number of electrodes	2 electrodes (1 pair of Bi-polar electrodes).	6 electrodes (3 pairs of Bi-polar electrodes).	Similar to Predicate Device. See note No. 1.

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Feature	EL Global *sensiLift* *New Device*	EndyMed *Newa™* [DEN150005] *Predicate Device*	Characteristics comparison (similarity)
Treatment areas	Face: lower cheek (perioral), upper cheek (periorbital) and under the chin.	Face: lower cheek, upper cheek and under the chin.	Identical
Treatment regimen	5 minute each area, 1 time per week, for 8 consecutive weeks (treatment area about 4X4 cm^2).	4 minute each area, 5 times per week, for 4 consecutive weeks (treatment area about 4X4 cm^2).	Different. Treatment regimen was validated via clinical Trial. See note No. 2.
Intended population	Adult healthy women (Fitzpatrick skin type I-IV) who desire to reduce facial wrinkles.	Adult healthy women (Fitzpatrick skin type I-IV) who desire to reduce facial wrinkles.	Identical
Use Environment	Home Use, self-operation by an unprofessional user.	Home Use, self-operation by an unprofessional user.	Identical
Device Features			
Hand piece Dimensions, (LXHXW) [mm^3]	173 X 56.8 X 53	73 X 37 X 120	Similar. See note No. 3.
Weight [gr]	122	70	Similar. See note No. 3.
Electrodes treatment area [mm^2]	176	178	Identical
Body contact materials	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, blue or green, reflecting the device status • Knob for energy level selection	Similar. See note No. 4.
Maximal power by hardware [Watt]	9 ± 1	10 ± 2	Identical
User selectable	3 energy levels deliver skin level power of:	2 energy levels, deliver skin level power of:	Similar. See note No. 1.

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Feature	EL Global *sensiLift* *New Device*	EndyMed *Newa™* [DEN150005] *Predicate Device*	Characteristics comparison (similarity)
energy levels (time modulation, pulse) [%]	• Level 3 - 72% • Level 2 - 55% • Level 1 - 38%	• Level 2 - 60% • Level 1 - 40%	
Safety mechanism	• Two redundant thermistors continuously monitoring skin temperature and automatically de-activate RF energy delivery when temperature of 40°C/ 104°F is detected, until temperature lowers enough. • Moving electrodes to prevent local over-heating. • A flickering or steady green LED light when the device is active. • RF is delivered only when both electrodes are with body contact.	• One Thermal sensor for skin temperature measurements. Automatically stop delivering RF when temperature of 42°C is detected, until temperature lowers enough. • Built in moving sensor stop delivering RF when the device is stationary • A steady LED when the device is active • Vibratory signal alerts when treatment period completed.	Similar. Usefulness of all safety mechanisms was validated in clinical trial and usability study. See note No. 4.
Performance Characteristics			
Electrical requirements	100-240 V, 50-60 Hz 9 V, 1.5 A	100-240 V 50-60 Hz 9 V, 2 A	Identical
Energy consumption	Up to 10W	Up to 10W	Identical
Frequency [MHz]	1	1	Identical
Safety standards			
Safety/ EMC	**IEC 60601-1:2005/EN 60601-1:2006**, General safety standard: safety	**IEC 60601-1:2005/EN 60601-1:2006**, General safety standard: safety	Identical. sensiLift has the same safety/ EMC certifications

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Feature	EL Global *sensiLift* *New Device*	EndyMed *Newa™* [DEN150005] *Predicate Device*	Characteristics comparison (similarity)
	requirements for medical electrical systems. **IEC 60601-1-2:2007**, **IEC 60601-1-2:2009**, Medical electrical equipment Part 1-2 - General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility – Requirements And Tests. **IEC 60601-1-11:2010**, 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: 2009**, 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.	requirements for medical electrical systems. **IEC 60601-1-2:2007**, Medical electrical equipment Part 1-2 - General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility – Requirements And Tests. **IEC 60601-1-11:2010**, Medical electrical equipment Part 1-11 – Requirements for the medical electrical equipment and medical electrical systems used in the home healthcare environment.	as the predicate device and is certified for additional standard.
Biocompatibility	All parts that are in contact with user comply with the requirements for **ISO-10993-1: 2009,** Biological evaluation of medical	All parts that are in contact with user comply with the requirements for **ISO-10993-1: 2009,** Biological evaluation of medical	Identical See note No. 5

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Feature	EL Global *sensiLift* *New Device*	EndyMed *Newa™* [DEN150005] *Predicate Device*	Characteristics comparison (similarity)
	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.	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.	
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.	Identical

Note No. 1. The energy delivered and electrodes architecture.

The method of RF delivery is the crucial factor, since it will dictate the penetration depth of the RF energy. Both sensiLift and predicate device are 1 MHz Bi-polar RF devices. The power energy output is an additional important factor for safe and effective treatment since it dictates the time required to achieve the desired heating. Both devices have similar maximal power consumption of up to 10 W and the effective delivered energy levels are set on time pulse basis (time modulation), with similar values for both devices.

The configuration of the electrodes affects the penetration depth of the RF energy as well as the treatment area and the current density. The differences in both devices configuration does not affect the safety and efficacy of the devices, as s

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was further demonstrated using varies EMC tests, in-vitro comparisons (Performance Testing – Bench) and a clinical trial (Performance Testing – Clinical).

Note No. 2. The treatment Regimen.

The treatment regimen of the sensiLift was especially planned to achieve its intended use in a safe and effective manner. Both sensiLift predicate devices are designed for the exact same anatomical site. Since the total exposure of the sensiLift device lower than of the predicate device, no safety issues are raised.
Both the safety and efficacy of the sensiLift device for home-use environment for the intended use was validated in a clinical trial (Performance Testing – Clinical).

Note No. 3. Device size and weight.

The size and weight of the hand-held device are basic unit characteristics with no effect over the intended use nor the safety nor the efficacy of the device. The sensiLift device was designed to allow ergonomic and fatigue-free grip during several minutes of treatments by the naïve user.

Note No. 4. User interface and safety mechanism.

Both user interface elements and the safety mechanisms the sensiLift device were designed to meet the needs of the naïve user at home and to protect its user from any hazard (including several safety mechanisms). The added feature of the sensiLift electrodes to move along their axis does not alter the intended use nor affect neither the safety profile nor introducing new or additional risk factors. This movement ability of the electrodes is similar to devices classified as class 1 devices, exempt of 510K (Massager, Therapeutic, Electric; Product Code ISA; Regulation Number 890.5660). The suitability of sensiLift device for home-use environment and ability of the naïve lay user to use the device in a safe and effective manner was verified according to safety standards and further validated

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in a Human Factors Test Validation (including self-screening) study and further validated in a clinical trial data (Performance Testing – Bench and Performance Testing – Clinical, respectively).

Note No. 5. Biocompatibility.

The sensiLift device is made of similar materials that come into contact with user's body as already cleared for the predicate device (DEN150005) and for the auxiliary device (K140527 and K161089).

11. CONCLUSIONS

Due to these identical clauses and high similarities, the sensiLift device is at least as safe and as effective as the predicate device, since they share the same intended use, technological characteristics, features, specifications and materials and anatomical site for use.

The differences between the sensiLift device and the predicate device do not raise new safety or effectiveness issues or questions, as detailed above.

Based on the performance testing and comparison to predicate devices, the *sensiLift* device is substantially equivalent to the previously cleared NEWA predicate device.