DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 14, 2017

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

Re: K170637
Trade/Device Name: sensiFirm
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX, GEI
Dated: May 21, 2017
Received: May 31, 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)*

K170637

Device Name
sensiFirm

Indications for Use *(Describe)*

The sensiFirm device is intended for the treatment of the following medical conditions using non thermal RF combined with massage:
Temporary reduction in the appearance of cellulite.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DATE PREPARED: MAY 21ST, 2016

1. 510(K) OWNER NAME

EL Global Trade Ltd.

Tzoran 8th st, P.O.Box 8242, Netanya 425068, Israel.

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

Contact person name: Dr. Yael Liebes-Peer, RA/ QA Manager (E mail: Yael@sensica.com) and Martin Gurovich, CEO (E mail: Martin@elglobalt.com).

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

2. DEVICE NAME

Common/Usual Name: OTC device for improvement in the appearance of cellulite

Proprietary/Trade name: *sensiFirm*

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

Device Category	Product Code	Regulation Number	Panel
Massager, Vacuum, Radio Frequency Induced Heat	PBX	878.4400	General and Plastic Surgery
Electrosurgical, Cutting & Coagulation & Accessories	GEI	878.4400	General and Plastic Surgery

3. PREDICATE DEVICES

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

3.1 InMode System MiniFX Handpiece by InMode MD Ltd. device, cleared under Premarket Notification K160329, dated August 19th, 2016.

3.2 V10 System, V-Form Handpiece by Viora Ltd. device, cleared under Premarket Notification K150035, dated May 1st, 2015.

4. DEVICE DESCRIPTION

The sensiFirm is an OTC, home use device, designed to deliver non-thermal RF energy and mechanical skin massaging. RF energy does not cause thermal damage to the treated skin and the subdermal adipose layer. The level of the non-thermal RF power, to achieve maximum comfort is user selectable. The ergonomic hand held device allows efficient treatment of the indicated body areas. It is a non-invasive, non-ablative device and it is supplied as non-sterile.

The sensiFirm device consists of power supply, RF power generator, Programmable Logic Controller (PLC, microcontroller) embedded in PCBA and user interface. The device also includes a vibration motor, four Bi-polar (2 pairs) electrodes and two redundant temperature sensors. The PLC (on the PCBA) is specially configured software combined with hardware circuits that provides the operational and safety function of the system.

The sensiFirm device is operated while continuously moving it over the treatment area. This ensures a uniform distribution of the non-thermal RF energy together with mechanical massage over the entire treatment area.

Device specifications:

- Maximal power output: 10±1 Watt.
- Skin level power: 6±1, 8±1 and 10±1 Watt (energy levels 1-3).
- Frequency: 1±0.05 MHz.
- Maximal temperature allowed: 41^0C/ 105.8^0F.

5. INTENDED USE/ INDICATIONS FOR USE

The sensiFirm device is intended for the treatment of the following medical conditions using non thermal RF combined with massage:

Temporary reduction in the appearance of cellulite.

6. NON-CLINICAL (BENCH) PERFORMANCE DATA

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

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

Bench testing was conducted according to IEC 60601 family of standards to demonstrate that the *sensiFirm* 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 (Verification and Validation):

- Over-heating safety. The two redundant temperature sensors embedded in the device constantly measure the skin temperature and deactivate RF delivery when temperature exceeds 41^0C/ 105.8^0F. 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 for the different power levels on a 150 Ω load, which is appropriate as the reference of the average load of the user, as well as on other impedance values and in overall relevant environmental conditions. The measured total power was within the

predefined 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)

The sensiFirm device complies with the following recognized standards for Electrical Safety and EMC testing:

- IEC 60601-1:2012/EN 60601-1:2013, 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 60601-2-2: 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.
- 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.

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 since inadvertent software errors could result in skin burns to the user.

Human Factors Validation Testing

A human Factors Validation Testing was done to evaluate the HFE/ UE (Human Factors Engineering/ Usability Engineering) 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 goal was to demonstrate that the typical OTC users can understand the device labeling (mainly the outer package) and correctly choose the sensiFirm device for themselves for its intended use. The study included three main questions regarding the intended use of the device, treatment areas and self-selection (the latter was acording to the contraindications), with possible answers: „Yes“or „No“, followed by explenation and further validation by the moderator. A total of 47 participants, 5 men and 42 women, from age 24 to 71 years old (average 42 ± 12 years old) were enrolled to this study. Participants had different educational levels, as obtained by REALM testing with 26% below 9th grade level. All participants had met the inclusion/ exclusion criteria and signed ICF. 100% of the participants had made the correct descion regarding the intended use of the device, 98% had correctly identified the treatment areas and 96% had reported correct answers, as further validated by the moderator (κ=0.91). Therfore, the success criteria of the primary enpoint was met.

Usability/ User Interface Study goal was to demonstrate the intended OTC user can correctly use the device, based on the labeling material for the intended aesthetic puspose. The study included four use scenarios including 21 relevant tasks: “getting to know the device and device set up” (7 tasks), “self-preparation” (4 tasks), “device usage” (7 tasks) and “after usage” (3 tasks). None of the participants 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, demonstrating rhe sucess criteria of the primary enpoint was met.

Furthermore, 62% of the participants (16 out of 26) had additionally commented that the device instructions are clear and that the use is easy and comfortable.

Participants were also asked regarding their user experience and satisfaction after this study, and high satisfaction was obtained, with an average result of 1.95±0.51, using a 1-5 discrete scale (when 1 represent best and 5 worst).

The human Factors Validation Testing , including both Labeling Comprehension/ Self-Selection Study and Usability/ User Interface Study, demonstrates that the potential 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 *sensiFirm* is a non-sterile, reusable device, intended for a single user. The device cleaning instructions are based on the cleaning instructions of the predicate devices due to the fact that both devices are made from the same materials are used similarly.

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

The biocompatibility evaluation for the *sensiFirm* 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 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

EL Global has categorized its *sensiFirm* 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.

9. CLINICAL PERFORMANCE DATA

The *sensiFirm* safety and efficacy for non-invasive temporary reduction in cellulite appearance, was examined in an open label, prospective, interventional single arm clinical study, in a home use environment.

33 women, age ranging between 29 to 63 years (average age 46 ± 9 years), fulfilling the inclusion criteria, were enrolled to the study by the Principle Investigator (PI). Participants treated one to three treatment areas, according to participants own preference and the PI's approval: 27 participants chose to treat the cellulite (buttocks, including one participant treated the inner thigh area), and 8 and 4 chose to treat the abdomen and arms regions, respectively resulting in total of 39 areas that had completed 8 sensiFirm treatments according to the instructions for use and appeared to the 3 months after treatments last follow-up (FU2).

The cellulite appearance was assessed using the Modified Neurenberg-Muller Cellulite Grading Scale and improvement was defined as decrease of at least one score in the Scale. This assessment was conducted by 3 evaluators (3 board certified dermatologists and plastic surgeons) at the end of the active treatment regimen (T8), as well as one and three months after the last treatment (follow-up regimen FU1 and FU2, respectively). A participant was considered a success if at least 2 out of the 3 independent evaluators agreed that the participant had shown at least one degree of improvement in the cellulite appearance (one score reduction in the Modified Neurenberg-Muller Cellulite Grading Scale) when comparing the score obtained at each time point (T8, FU1 and FU2) to the baseline score ("subject as her own control"). In addition, a concurrent control was used, and only one side of the body (e.g. left buttocks) was treated to allow comparison to the other untreated side (e.g. right buttocks).

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, 93%, 96% and 100% of the study participants (according to agreement between at least 2 out of the 3 evaluators) have shown an improvement in overall cellulite appearance of the treated side at T8, FU1 and FU2, respectively. This improvement was manifested in an average reduction of -1.28, -1.59 and -1.78 in the Modified Neurenberg-Muller Cellulite Grading Scale, at T8, FU1 and FU2, respectively. In contrast, the untreated (control) side remained unchanged during the course of the study.

Effectiveness was also assessed according to the participants' satisfaction as recorded by the satisfaction questionnaire which was filled by all the participants at each follow-up visit. 95% of the participants (average value for after the last active treatment and follow-ups) were generally satisfied with the device. 94%

had reported on improvement in their skin's appearance, 89% had reported on improvement in cellulite appearance and skin tightening and 90% had reported on skin texture improvement. In addition, the participants found the device easy to use, with 82% stating using sensiFirm was clear and simple, 93% and 89% stating that reaching the treatment areas and holding the device was comfortable, respectively, and 96% replied that a regime of total of 8 treatments was reasonable (all percentages refer to T8 visit). All participants found the device to be painless or discomfort less. At the last follow-up (FU2), participants were also asked whether they would like to continue using the device for the other untreated side and whether they would like to treat additional anatomical areas. All participants answered YES to these two questions.

To summarize, these results demonstrate that the device is safe and effective for the intended use under anticipated conditions of use (home environment).

10. SUBSTANTIAL EQUIVALENCE

The indications for use and technological characteristics of the sensiFirm device are substantially equivalent to the indications for use and technological characteristics of the predicate device. A detailed comparison between the sensiFirm 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.

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

Feature	**EL Global** ***sensiFirm*** *New Device*	**InMode MD** ***MiniFX/ InMode*** [K160329] *Predicate Device #1*	**Viora** ***V-FORM/ V10*** [K150035] *Predicate Device #2*	**Characteristics comparison (similarity)**
Regulatory classification				
Device Class	Class II	Class II	Class II	Same
Classification Panel	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery	Same

Feature	EL Global *sensiFirm* *New Device*	InMode MD *MiniFX/ InMode* [K160329] *Predicate Device #1*	Viora *V-FORM/ V10* [K150035] *Predicate Device #2*	Characteristics comparison (similarity)
Product code	PBX, GEI	PBX, GEI	PBX, ISA	Same as Predicate Device #1
Regulation number	• 21 CFR 878.4400 • 21 CFR 878.4400	• 21 CFR 878.4400 • 21 CFR 878.4400	• 21 CFR 878.4400 • 21 CFR 890.5660	Same as Predicate Device #1
Device Category	• Massager, Vacuum, Radio Frequency Induced heat • Electrosurgical, Cutting & Coagulation & Accessories	• Massager, Vacuum, Radio Frequency Induced heat • Electrosurgical, Cutting & Coagulation & Accessories	• Massager, Vacuum, Radio Frequency Induced heat • Massager, Therapeutic, Electric	Same as Predicate Device #1
Regulation description	• Electrosurgical cutting and coagulation device and accessories • Electrosurgical cutting and coagulation device and accessories	• Electrosurgical cutting and coagulation device and accessories • Electrosurgical cutting and coagulation device and accessories	• Electrosurgical cutting and coagulation device and accessories • Therapeutic massager	Same as Predicate Device #1
Intended use	The sensiFirm device is intended for delivering non thermal RF combined with massage for temporary reduction in the appearance of cellulite	The InMode System (with MiniFX Handpiece) is intended for delivering non thermal RF combined with massage for temporary reduction in the appearance of cellulite	The V-Form Handpiece (with BC and FC applicators) is indicated for delivering non thermal RF combined with massage for temporary reduction in the appearance of cellulite	Same
Device Characteristics				
Mode of operation	Mechanical (vibration) massage combined with RF energy emitted from Bi-polar electrodes via a delivery Handpiece	Mechanical vacuum massage combined with RF energy emitted from Bi-polar electrodes via a delivery Handpiece	Mechanical vacuum massage combined with RF energy emitted from Bipolar electrodes via a delivery Handpiece	Similar. Note No. 1.
Energy Source	RF (Bi-polar), 1 MHz	RF (Bi-polar), 1 MHz	RF (Bi-polar), 0.8, 1.7, and/ 2.45 MHz	Same as predicate Device #1. Note No. 2.
Number of electrodes	4 electrodes (2 pairs)	2 electrodes (1 pair)	6 or 4 electrodes (3 or 2 pairs, for BC or FC applicators, respectively)	Note No. 2.
Massage	Vibrational massage (1000 rpm, 1.5 [g]) assisted by manual manipulation	Mechanical vacuum massage, with pulsed vacuum (300 - 500 mbar)	Mechanical vacuum massage, with pulsed vacuum (up to 500 mbar)	Different mechanism, since vacuum technology present safety risks for home

Feature	EL Global *sensiFirm* *New Device*	InMode MD *MiniFX/ InMode* [K160329] *Predicate Device #1*	Viora *V-FORM/ V10* [K150035] *Predicate Device #2*	Characteristics comparison (similarity)
				use environment. Note No. 1.
Treatment areas	Cellulite areas (buttocks, thigh, upper legs)	Cellulite areas (buttocks, thigh, upper legs)	Cellulite areas (buttocks, thigh, upper legs)	Same
Treatment regimen	20 minutes per each area, 1 time per week, for 8 weeks	1 time per week, for 6 weeks. * Information according to reference #17, see Appendix F, VOL 003.	20minutes per each area, 1 time per week for 8 weeks. * Information according to reference #5, see Appendix F, VOL 003.	Similar. Treatment regimen was validated via clinical Trial. Note No.3.
Intended population	Adult people who desire to improve their body appearance	Adult people who desire to improve their body appearance	Adult people who desire to improve their body appearance	Same
Use Environment	Home Use, self-operation by an untrained user.	Aesthetic Clinic	Aesthetic Clinic	Validated in a Human Factors tests and in a Clinical Trial. Same as auxiliary device. Note No. 4.
Device Features				
Hand piece Dimensions	146 X 74 X 63 mm^3/ 5.7 X 2.9 X2.5 $inch^3$	Unknown	230 X 230 X 95 mm^3/ 9.1 X 9.1 X 3.7 $inch^3$ or 230 X 230 X 65 mm^3/ 9.1 X 9.1 X 2.6 $inch^3$, BC or FC applicators, respectively	Similar. Note No. 4.
Weight	192 gr/ 0.42 lb	Unknown	930 gr/ 2.05 lb or 750 gr/ 1.65 lb, BC or FC applicators, respectively)	Similar. Note No. 4.
Electrodes treatment area [mm^2]	~2000 (calculated according to: 2×33×30), where – • 2 – numbers of electrodes pairs • 33 - average distance between electrodes is 33 mm • electrodes length 30 mm	Unknown. Distance between electrodes is 25 mm.	6200 or 450 (BC or FC applicators, respectively)	Similar. Note No. 2.
Device main components	Power adaptor, hand-held handpiece	Console, MiniFX handpiece	Console, V-FORM handpiece	Similar. Note No. 4.
User interface	• 4 LEDs: • 3 green LEDs for visualizing the RF energy level	• Touch screen (main console) • Different audible beeping	• Touch screen (main console) • Audible sound indications at various	Different. Note No. 4.

Feature	EL Global *sensiFirm* *New Device*	InMode MD *MiniFX/ InMode* [K160329] *Predicate Device #1*	Viora *V-FORM/ V10* [K150035] *Predicate Device #2*	Characteristics comparison (similarity)
	• 1 green/ orange/ red LED reflecting the device status • Button for energy level selection • The massage achieved by the vibration motor makes audible sound and the sensation of massage itself make the user aware of treatment being delivered.	sounds when the suction is adequately coupled and the RF is being administered and according to different temperature measured	points of the treatments	
Energy levels (maximal and user selectable)	Up to 10 Watts. 3 energy levels (software and hardware limited): 6, 8 or 10 Watts, depending on the user selection.	10-25 Watts	Up to 25 or 50 Watts (for FC or BC handpiece, respectively). 4 energy levels	Similar. Note No. 2.
Safety mechanism	• 2 redundant thermal sensors for skin temperature measurements. Automatically stop delivering RF when temperature of 41°C/ 105.8°F is detected, until temperature lowers to 40.5°C/ 104.9°F (hysteresis). • Device automatic test for proper skin contact prior to release a pulse (using a short and low energy pulse) • The vibrational massage being delivered reflects to the user the device is active • A steady LED when the device is active	• Integrated IR thermometer, with maximal temperature (skin surface 41°C/ 105.8°F)	• Integrated IR thermometer • Default treatment parameters automatically suggested • A trigger requires pressing prior to emitting energy • Device automatic test for proper coupling prior to release a pulse (using a short sub-pulse) • Proper connection of the handpiece, otherwise alert	Similar to auxiliary device. Usefulness of all safety mechanisms was validated in clinical trial and usability study. Note No. 4.
Electrical requirements	100-240 V 50-60 Hz	100-240 V 50-60 Hz	100-240 V 50-60 Hz	Same
Safety standards				
Safety/ EMC	• IEC 60601-1:2012/EN 60601-1:2013 • • IEC 60601-1-2: 2014	• IEC 60601-1:1988 (Am. 1 1991 + Am. 2 1995) • IEC 60601-1-2: 2001	• IEC 60601-1 • EC 60601-1-2	Same, with additional safety standard (60601-1-11)

Feature	EL Global *sensiFirm* *New Device*	InMode MD *MiniFX/ InMode* [K160329] *Predicate Device #1*	Viora *V-FORM/ V10* [K150035] *Predicate Device #2*	Characteristics comparison (similarity)
	• IEC 60601-2-2: 2009 • IEC 60601-1-11:2015	• IEC 60601-2-2: 2006	• IEC 60601-2-2	for home use environment
Biocompatibility	All parts that are in contact with user comply with the requirements of ISO-10993-1.	All parts that are in contact with user comply with the requirements of ISO-10993-1.	All parts that are in contact with user comply with the requirements of ISO-10993-1.	Same
Software	The software was verified and validated according to the FDA guidance.	The software was verified and validated according to the FDA guidance.	The software was verified and validated according to the FDA guidance.	Same

Note No. 1. The massage Type

There are several methods commonly used for massaging, including: manual massage, pressuring, vibrations, rollers assisted, vacuum assisted etc. Vibration assisted massage offers safe and localized treatment with similar therapeutic effect. Such devices are classified as class I devices and are 510(K) exempt (product code IRO or ISA).

Note No. 2 - The Energy Delivered and Electrodes Architecture

Treatment with all of the devices (sensiFirm and both predicate devices) utilizes the same technology of Bi-polar RF, on the same anatomical sites and for the same purpose. Generally, safety and efficacy of the device for the intended use is affected by the method of RF delivery, power energy output and the configuration/ area of the treatment electrodes. All these factors were taken into account when designing the treatment protocol, which has been validated in a clinical trial.

Note No. 3 - The Treatment Regimen

The treatment regimen of the sensiFirm was especially planned to achieve its intended use in a safe and effective manner. Both sensiFirm and its predicate devices are designed for the exact same anatomical sites, with similar treatment

protocols. Though the treatment protocols are different, the total exposure to the sensiFirm device throughout the entire treatment regimen is identical to predicate device #2 and similar to predicate device #1. Therefore, no issues in means of safety for the user are raised. Furthermore, the efficacy was validated in a clinical trial.

Note No. 4 – Applicability to Home Use Environment

While the sensiFirm was designed for OTC home use, both predicate devices are prescription devices, to be used in a clinic by a professional operator. Auxiliary device (Newa by EndyMed Medical Ltd., cleared under DEN 150005) supports the OTC home use environment. Several device's features, all related to its design and usability elements, were specially tailored for the home use environment, which was tested in a Human Factors Test study and further validated in a clinical trial.

11. CONCLUSIONS

Due to these identical clauses and high similarities, the sensiFirm device is at least as safe and as effective as the predicate device. The differences between the sensiFirm device and the predicate device do not raise new safety or effectiveness issues or questions, as detailed above.

The performance specifications of the *sensiFirm* (i.e., RF frequency and RF power) are substantially equivalent to those of the predicate devices. The safety features and compliance with safety standards of both 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 *sensiFirm* 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.

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