July 24, 2018

EL Global Trade Ltd
Martin Gurovich
CEO
Tzoran 8th St, P.O. Box 8242
Netanya, 4250608 Israel

Re: K181095
Trade/Device Name: RF-Relief
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX, GEI
Dated: April 15, 2018
Received: April 26, 2018

Dear Martin Gurovich:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

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)*

K181095

Device Name
RF-Relief

Indications for Use *(Describe)*

The RF-Relief is an over the counter hand held device intended to emit energy in RF spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscular and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local blood circulation, and temporary relaxation of muscles.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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RF-Relief – 510K Submission	RD-12073 A0

510(K) SUMMARY

DATE PREPARED: JULY 24, 2018

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: ra_qa@homewellt.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 topical heating device for pain relief

Proprietary/Trade name: *RF-Relief*

Classification: EL Global Trade Ltd.'s *RF-Relief* 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 SensiFirm by EL Global Trade Ltd., cleared under Premarket Notification K170637, dated July 14, 2017.

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

3.3 InMode Plus System by InMode MD Ltd., cleared under Premarket Notification K153568, dated July 12, 2016.

4. DEVICE DESCRIPTION

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

The RF-Relief device is operated while continuously moving it over the treatment area. This ensures a uniform distribution of the 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, respectively).
- Frequency: 1±0.05 MHz.
- Maximal temperature allowed: 41^0C/ 105.8^0F.

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5. INTENDED USE/ INDICATIONS FOR USE

The RF-Relief device is an over the counter hand held device intended to emit energy in the RF spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscular and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local blood circulation, and temporary relaxation of muscles.

6. NON-CLINICAL (BENCH) PERFORMANCE DATA

The following performance data (bench tests) were provided in support of the performance, safety and efficacy of the RF-Relief 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 RF-Relief 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

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(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 RF-Relief 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.

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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.

Performance testing- temperature during treatment

The temperature measurement of the skin during treatment showed that when the device is operated according to instructions for use and in all treatment modes, a safe and effective temperature for its intended use, around 41°C, is reached and maintained over 10-20 minutes on all skin types.

Labeling comprehension/ Self-Selection study

Demonstrated that intended OTC users can understand the package labeling and correctly choose this device for themselves for the indicated aesthetic use.

Usability/ User interface study

Evaluated usability performance for intended use.

7. PERFORMANCE TESTING - ANIMAL

No animal testing was performed with the subject device

8. CLEANING, STERILIZATION, SHELF LIFE AND BIOCOMPATIBILITY

The RF-Relief 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 and are used similarly.

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

The biocompatibility evaluation for the RF-Relief 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 RF-Relief 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

No clinical data is included in this submission.

10. SUBSTANTIAL EQUIVALENCE

The indications for use and technological characteristics of the RF-Relief device are substantially equivalent to the indications for use and technological characteristics of the predicate devices.

The design, components, specifications and performance specifications of the RF-Relief device are identical to the ones of the sensiFirm predicate device and are of high similarity to the InMode System MiniFX Handpiece and InMode Plus System predicate devices. All devices are based on RF energy (Bi-polar source delivering

1 MHz frequency and similar intensity and power) with the same mechanism of action. The technological component (i.e. the vibration massage) incorporated in the RF-Relief device, is the same as in the sensiFirm predicate device. This feature does not alter the functionality and performances of the RF-Relief device compared to predicate devices since it does not affect the RF performances and the predetermined temperature. All these features and characteristics supports the suitability of the RF-Relief to its intended use.

The safety features and compliance with safety standards of both the RF-Relief device and its predicate devices are identical.

All patient contact materials are identical to the materials found in the sensiFirm predicate device, which was tested and found to be in compliance with the ISO 10993-1 standard.

The minor differences in the technological characteristics do not raise new safety or effectiveness concerns and are demonstrated to be substantially equivalent through bench testing. Furthermore, RF-Relief 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. These performance tests demonstrated that the device specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the RF-Relief device is substantially equivalent to the predicate devices selected: the sensiFirm device, cleared under K170637, the InMode System MiniFX Handpiece cleared under K160329 and the InMode Plus System, cleared under K153568.

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11. CONCLUSIONS

Based on the performance testing and comparison to predicate devices, the RF-Relief device is substantially equivalent to the previously cleared predicate devices.