November 6, 2020

Triworks Group S.r.l.
% Parul Chansoria
Elexes Medical Consulting
453 West San Carlos Street
San Jose, California 95110

Re: K192621
Trade/Device Name: Medical RF
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 2, 2020
Received: October 2, 2020

Dear Parul Chansoria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192621

Device Name
Medical RF

Indications for Use *(Describe)*
The Medical RF is a non-invasive device intended for use in Dermatologic and General Surgical non-invasive treatment procedures of wrinkles and rhytides for I to IV Fitzpatrick Skin Types

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
K192621

5.1 Submitter's Information

Triworks Group S.r.l.
Registered Office: Via L.Belpulsi 3-86100 Campobasso, Italy
Operating Office: Via Don G.Mucciardi 5-86020 Campochiaro (CB), Italy

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Summary Prepared: Nov 3, 2020

5.2 Device Information

Common/ Usual Name: Electrosurgical, cutting and coagulation and device and accessories
Trade Name: Medical RF
Regulation Name: Electrosurgical, Cutting & Coagulation & Accessories
Regulatory Class: Class II
Classification Panel: General & Plastic Surgery
Product Code: GEI
Regulation Number: 21 CFR 878.4400

5.3 Predicate Device Information

The Medical RF (Subject Device) is substantially equivalent to the following cleared devices:

Company	Predicate Priority	Product	510(k) Number
Alma Lasers, Ltd.	Primary Predicate	Accent	K070004
Lumenis, Inc	Secondary Predicate	Aluma Skin Renewal System	K051214
BTL Industries, Ltd.	Tertiary Predicate	Exilis	K092191

5.4 Device Description

The Medical RF is a non-invasive device intended for use in Dermatologic and General Surgical non-invasive treatment procedures of wrinkles and rhytides for I to IV Fitzpatrick Skin Types.

The mechanism of action of the Subject Device involves the delivery of thermal energy to the subcutaneous tissue and the deep dermis. The Device utilizes the electromagnetic waves originated from two poles: a single electrode on the handpiece that contacts the skin and a

grounding reference plate (monopolar RF), or two electrodes of the handpiece placed over the treatment area (bipolar RF).

Medical RF is equipped with three types of handpieces: Two monopolar handpieces (small and medium) and one bipolar handpiece; all of them contain a sensor temperature used by the DTC (Derma Temperature Control) technology. The DTC is an innovative system that instantly detects the temperature of the skin and regulates the power emissions to maintain (at the same value) the transferred temperature of RF during the treatment.

The DTC system allows the operator to know the real-time temperature of the skin surface, there is no further need to manually regulate the power according to the temperature changes during the treatment session. DTC technology ensures the safety and effective functioning of the Subject Device. The user always knows the real-time temperature on the skin during the treatment and does not have to manually change the power emissions in relation to the patient's perception of heat, thereby improving the efficacy of the treatment.

The Subject Device is recommended to be used by trained and qualified personnel only and includes a dedicated software (interface RS-232), installed by the manufacturer in the device's memory.

5.5 Indications for use

The Medical RF is a non-invasive device intended for use in Dermatologic and General Surgical non-invasive treatment procedures of wrinkles and rhytides for I to IV Fitzpatrick Skin Types.

5.6 Technological Characteristics w.r.t Predicate Devices

The Indications for Use, key technological characteristics, and operating principle of the Subject Device (Medical RF) are equivalent to the Primary and the Secondary Predicate Devices.

Table 2: Substantial Equivalence w.r.t. Predicates

Title	Subject device	Primary Predicate	Secondary Predicate 1	Tertiary Predicate 2	Comparison
Manufacturer	Triworks Group S.r.1	Alma Lasers Ltd.	Lumenis Inc.	BTL Industries Ltd.	---
Device Name	Medical RF	Accent	Aluma Skin Renewal System	Exilis	---
510(k) Number	K192621	K070004	K051214	K092191	---
Product Code	GEI	GEI	GEI	GEI	Equivalent

Regulatory Number	878.4400	878.4400	878.4400	878.4400	Equivalent
Regulatory Class	II	II	II	II	Equivalent
Indications for Use	The Medical RF is a non-invasive device intended for use in Dermatologic and General Surgical non-invasive treatment procedures of wrinkles and rhytides for I to IV Fitzpatrick Skin Types.	The Accent is intended for use in Dermatologic and General Surgical procedures for non-invasive treatment of wrinkles and rhytides using combined treatment with Unipolar and Bipolar.	The Aluma Skin Renewable System is a non-invasive device intended for use in Dermatologic and General Surgical procedures non-invasive treatment of wrinkles and rhytides.	The EXILIS device is indicated for use in non-invasive dermatologic and general surgical procedures.	Equivalent
Performance Characteristics					
Energy source	Radiofrequency	Radiofrequency	Radiofrequency	Radiofrequency	Equivalent
RF Power	200 W	200 W-300 W	2 W-10 W	170 W	Same as Primary Predicate and similar to Tertiary Predicate
Output Radiofrequency	470 KHz	40680 KHz (±2 KHz)	468 KHz	3400 KHz	Similar with Primary and Secondary Predicates as it falls within the range of the Primary Predicate, and the range of Secondary Predicate is slightly lower than the Subject Device.
Input Voltage	110-240 VAC 50-60 Hz	100-120 VAC, 5 A, 50-60 Hz 208-240 VAC, 5 A, 50-60 Hz	120 VAC ± 10%, 60 Hz, 12A	110-240 VAC 50-60 Hz	Equivalent

RF Handpiece	Bipolar, Monopolar (small and medium)	Bipolar, Unipolar (monopolar)	Bipolar (small and large)	Unipolar (monopolar)	Same as primary Predicate and similar to Secondary and tertiary Predicates.
Waveforms	Radiofrequency currents having frequency, time, modulation, and circulation as decided by the operator according to the specific medical protocol defined by the therapy.	Radiofrequency currents having frequency, time, modulation, and circulation as decided by the operator according to the specific medical protocol defined by the therapy.	Radiofrequency currents having frequency, time, modulation, and circulation as decided by the operator according to the specific medical protocol defined by the therapy.	Radiofrequency currents having frequency, time, modulation, and circulation as decided by the operator according to the specific medical protocol defined by the therapy.	Equivalent
Programmable Logic Controller	PIC (Programmable Interface Controller) providing the safety function of the system	Programmed treatment protocols	PLC providing the safety function of the system	DTC providing the safety function of the system	Different but does not raise new questions of safety or efficacy because the DTC of the Subject Device (Medical RF) detects instantly the temperature of the skin surface and consequently regulates the power emission.

5.7 Performance Data

Medical RF complies with the applicable standards for Electrical Safety, Electromagnetic Compatibility, and Biocompatibility to demonstrate the safety and effectiveness of the device.

Results of the clinical testing demonstrated that the Subject Device is safe and effective for its intended use. The supplied Instructions for Use provide the user with the applicable warnings and cautions during use. There are no new safety or effectiveness issues related to this device.

5.8 Clinical Evaluation

The clinical evaluation was conducted on a total of 40 samples (two samples from each of the 20 patients, performed by two physicians). The study population consisted of both genders, within the age range of 33 to 68, in good health. The study was designed by considering the real scenario of the aesthetic treatments with RF energy, and to include all types and degrees of skin wrinkles, rhytides, and other imperfections. An improvement of wrinkles was evaluated by a score value which was assessed by the doctors, following the examination of the treated areas and the related photos, before and after treatments, in accordance with the Fitzpatrick Wrinkle Assessment (for I to IV Fitzpatrick Skin Types) or Glogau scale. Any wrinkle score improvement (downgrade score >1) following the last treatment and at the follow-up visit, relative to pre-treatment wrinkle (baseline) score, was considered a success. The study revealed no adverse events, during the follow up of 4 to 6 months after the conclusion of the treatment.

The assessment for side effects was made by visually assessing skin responses, including edema, erythema, scarring, hypopigmentation, hyperpigmentation, and textural changes immediately after the treatment. Adverse event outcomes were calculated by each physician according to the level of pain perceived by the patients; the subjects were asked to rate their pain on a 0 to 4 scale. Almost all patients marked the pain level with a 0 or 1 score, which corresponds to a slight sensation of discomfort and/or pain.

All the 20 patients enrolled had successfully completed the treatments. Analysis of photographic results reveals improvements in facial wrinkles (downgrade of at least 1 score, according to the Fitzpatrick scale) in all (100%) patients according to the clinical assessment. Score differences were found to be statistically significant while comparing baseline scores to the scores obtained at the end of treatment ($p<0.05$) and at the follow-up visit ($p<0.05$), thus confirming the treatment efficacy. At the follow-up visit in four/five/six months, the subjects reported the same or additional improvements of facial wrinkles.

The results obtained showed improvement in the appearance of wrinkles. The study confirms that treatment using the Medical RF system is safe and effective for the improvement of wrinkles and rhytides.

5.9 Conclusion

Medical RF is substantially equivalent to the Predicate Devices in terms of technological characteristics, performance characteristics, system operating ranges, user interface characteristics and intended use. Performance testing demonstrates that Medical RF is as safe and effective as the Predicate Devices.