September 30, 2020

Vupiesse S.R.L
% Chuck Mograbi
Regulatory Affairs - Director
Silicus Technologies
2700 Post Oak Blvd #1625
Houston, Texas 77056

Re: K192077
Trade/Device Name: Tua Face Fitness / Tua Trend Face
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: September 17, 2020
Received: September 17, 2020

Dear Chuck Mograbi:

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,

Vivek Pinto, PhD
Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K192077

Device Name
Tua Face Fitness / Tua Trend Face

Indications for Use *(Describe)*

Tua Face Fitness / Tua Trend Face is a device intended for facial stimulation and is indicated for Over-the-Counter cosmetic use.

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 - K192077

for Tua Face Fitness / Tua Trend Face

This 510k Summary is being submitted by the requirements of 21 CFR 807.92

1. **Submitter**

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2. **Contact Details for Correspondence in the USA**

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Prepared On:	September 28, 2020

3. **Device Name**

Trade Name of Device:	Tua Face Fitness /Tua Trend Face
Common Name:	Facial Stimulator
Regulation Number:	21CFR 882.5890
Regulation Description:	Transcutaneous Electrical Nerve Stimulator for Pain Relief
Product Code:	NFO
Device Class:	2

4. **Identification of Equivalent Legally Marketed Device**

510(k) Number:	K103031
Clearance Date:	11/10/2011
Regulation Number:	21CFR 882.5890
Manufacturer:	Bio-Medical Research, LTD
Trade Name:	BMR Face
Product Code:	NFO
Device Class:	2

5. Description of Device

Tua Face Fitness /Tua Trend Face*:

*Tua Face Fitness is the same device and has the same label as the "Tua Trend Face. Tua Face Fitness name was added for marketing purpose to designate it for the distribution in the USA.

Tua Face Fitness /Tua Trend Face is a two-channel, battery-operated cosmetic device which is intended for use on the face. The device comprises a rechargeable electronic device which connects to an applicator wand that delivers electrical impulses to the face.

The device operates by applying Transcutaneous Electrical Nerve Stimulation to the facial area. It means that the electrodes that are positioned on the skin must be wet with tap water to be conductive to generate of the electric pulses. The pads are made of pure cellulose backed by PVC. It is a surface device which comes in contact with skin. The duration of contact is less than or equal to 24 hours.

Description of Device Software.

The software of the Tua Face Fitness / Tua Trend Face use five programs or 5 zone locations with a total time of 10 minutes on one side of the face skin, this represent twenty minutes total when the client operate the device on the two sides of the face location. (ten minutes for the right side of the face sken and additional ten minutes for the left side). The client would choose the program of the specific zone (1 to 5) and the intensity of the program based on their preferences.

Tua Face Fitness / Tua Trend Face shows these five zones/ programs on high definition display, as you can see in the screen in the attached device's description document that the five programs and its location are pre-programmed in the CPU Circuit board with specific parameters such as stimulation frequency, pulse width, contraction times and recovery times; The pre- programmed characteristic are part of the CPU circuit board and it cannot be changed or controlled by the client. The client can only control the zone location, and the stimulation intensity of the micro-current through an up and down buttons, below the display of the device.

When the device is activated, The high definition displays Program 1, the time of two minutes is stated on the right upper corner, the client choice of the adjustable intensity (20–60) is stated on the left lower corner as 20, and the area of program one is the left upper cheek. The client can start this program by pressing "OK"

The total time for the five-program is 10 minutes for one side of the face (2 minutes each). When the intensity of the micro-current has been adjusted up or down during the application, the intensity is recorded in the program's memory for each program. The client then can repeat the same five programs on the other side of the face for 10 minutes and the right side and use the same recorded/save intensity. This feature will provide a visual direction and consistent operation on both sides of the face, making no other change.

The total duration for a full application is 20 minutes: (5 programs X 2:00 minutes each) X 2 sides of the face = 20 minutes. The same as the BMR predicate device.

The device recommended operating time is ranged from two minutes for one zone to 20 minutes for both sides of the face skin zones.
Description of the Operation Voltage
The Tua Face Fitness /Tua Trend Face uses a low voltage 4.8 V researchable battery to operate the device. The device/s charger will not recharge the battery while the device is in an operating mode., The battery & rechargeable component specifications were submitted to the FDA "K192077".

6. Statement of Intended Use/Indications for Use

Tua Face Fitness/Tua Trend Face is intended for facial stimulation and is indicated for Over the Counter Cosmetic Use.

7. Summary of Technological Characteristics

We have demonstrated the new device Tua Face Fitness/Tua Trend Face substantially Equivalent to the legally marketed predicate device BMR as part of this 510k submission. Table 5.1 below provides a summary comparison of technological characteristics of Tua Trend Face (Tua Face Fitness) versus that of the predicate "BMR Face."
There are no new technological characteristics that could affect the safety or effectiveness of Tua Trend Face / Tua Face Fitness.

8. Basic unit characteristics

Table 5.1 Summary comparison of Technological features of Tua Face Fitness/Tua Trend Face versus BMR Face (predicate device)

	Tua Trend Face (Tua Face Fitness)- (new device)	**BMR Face (predicate device)**
Intended use	Tua Face Fitness/Tua Trend Face is intended for facial stimulation.	BMR Face is intended for facial stimulation.
Device Class	Class II	Class II
Indications for use	Tua Face Fitness/Tua Trend Face is intended for facial stimulation and is indicated for Over the Counter Cosmetic Use.	BMR Face is intended for facial stimulation and is indicated for Over the Counter Cosmetic Use.
Target population	Healthy Adults	Healthy adults
Treatment area	Facial skin	Facial skin
Location used	Portable–used at home	Portable–used at home
Operating Power	4,8V DC rechargeable battery	3,6V rechargeable batteries
Materials	Same for a plastic case, electrodes caps constructed of PVC and wet pure cellulose for skin conduction.	Plastic case built of abs, electrodes of skin conductive through adhesive hydrogel layer.
Number of output modes	Five programs/zones delivered: 10.0 Minutes for 5 zone/ one side. 20.0 Minutes for 5 zone/both sides 2:0 Minutes per zone.	3 programs delivered: 20.0 Minutes 10.0 Minutes, 5.0 Minutes

Number of output channels	Two Chanels	Two Chanels
Silent Use Mode	Yes	Yes
Automatic Shut Off	Yes	Yes
Intencity Control Scale	0.0 to 60	0.0 to 100
Biocompatibility	Facial Wand comply with ISO 10993-1 “Biological evaluation of medical devices” ISO 10993-5: Tests for in vitro cytotoxicity, ISO 10993-10: Tests for irritation Intracutaneous; Skin sensitization; Cytotoxicity-Elution method.	Gel pads comply with ISO 10993-5 and ISO 10993-10.
Regulated current or regulated voltage	Rechargeable Battery is regulated through intensity control.	Rechargeable Battery is regulated through intensity control.
Compatibility with Electrical. Environmental and General Requirement.	Complies to IEC 60601-1-2 Medical electrical equipment - Part I-2: General requirements for safety–Collateral standard: Electromagnetic compatibility - Requirements and tests.	Complies to IEC 60601-1-2 Medical electrical equipment - Part I-2: General requirements for safety–Collateral standard: Electromagnetic compatibility -Requirements and tests.
Sterility	Non-Sterile	Non-Sterile
Electrical safety	Complies to IEC 60601-1 Medical electrical equipment–Part 1 General requirements for safety & IEC 60601-2-10 Medical electrical equipment–Part 2:10; Particular requirements for the safety of nerve and muscle stimulators.	Complies to IEC 60601-1 Medical electrical equipment–Part 1 General requirements for safety & IEC 60601-2-10 Medical electrical equipment–Part 2:10; Particular requirements for the safety of nerve and muscle stimulators.
Compliance* with 21 CFR 898	Yes	Yes
Mechanical safety	Complies to IEC 60601-1 & IEC60601-2-10	Complies to IEC 60601-1 & IEC60601-2-10
Thermal safety	Complies to IEC 60601-1 & IEC60601-2-10	Complies to IEC 60601-1 & IEC60601-2-10
Radiation safety	Non-applicable	Non-applicable
Electrical Charger	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10 charger IEC 60950	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10 charger IEC 60950
Software	Class A low risk designation. Completed based on the “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”	Completed based on the “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”

Software Programs	5 program/zones. 20 , 10 minutes and 2 minutes.	3 programs 20, 10 and 5 minutes.
Program Control	Intensity, Time, and Silent mode.	Intensity, time, and Silent mode.
Program Memory	Yes, Memory Function	Yes, Memory Function
Design	Device contains a control unit, an applicator, spare parts electrodes caps, charger, instructions for use.	The device contains a control unit, an applicator, gel pads, charger and instruction for use.
User interface	The user interfaces with the hand-held electrodes wand. The user also interacts with the control unit - On/off/pause button, and the choice of program mode such as increase or decrease intensity on the device.	The user interfaces with the control unit, applicator, and gel pads. The user interacts will the control unit - On/off/pause button, increase or decrease intensity on the left and right-hand sides of the device.
Indicator Display?	Yes	Yes
Patient Override control?	Yes	Yes
ON/Off Status	Yes	Yes
Low Battery Indicator	Yes	Yes

9. **Device Output specifications** (related to Prog. #1)

	Tua Trend Face / Tua Face Fitness (new device)	**BMR Face (predicate device)**
Mode or program names	Programs N°1, 2, 3, 4, 5	P1, P2, P3
Waveform	biphasic symmetrical	biphasic symmetrical
Shape (output voltage – resistive load)	Sinusoidal	Rectangular
Maximum output voltage (V) (+/- 10%)	19,1 @500 Ω 36,8 @2 KΩ 69,5 @10 KΩ	15 @500 Ω 60 @2 KΩ 32 @10 KΩ
Maximum output current (mA) (+/-10%)	38,2 @500 Ω 18,4 @2 KΩ 6,95 @10 KΩ	30 @500 Ω 30 @2 KΩ 3,2 @10 KΩ
Duration of primary phase (depolarizing) (µS)	75uS	100uS
Pulse duration (positive+ negative) (µS)	150uS	160-200uS
Frequency of modulation (Hz)	20-40-80	70-80
Net charge (per pulse)	Zero (biphasic symmetrical)	Zero (biphasic symmetrical)
Max phase charge @500Ω (µC)	5,73	6
Max current density (mA/cm², r.m.s.) @500Ω	1,31	1
Max average current (mA) @500Ω	5,95mA	4,1mA
Max average Power Density (W/cm²)	3,91 W/ cm²	3,91 W/ cm²

The carrier frequency, its shape and waveform are the same for all the programs. (see waveform Specification on table below; The same for the max values of voltage, current, net charge, max phase charge, max current density, max average current, max average power density). These are pre-programed into the device's Central Process, except the intensity which is control by the client to reduce or increase the intensity through upper or lower arrow button (The intensity represents the duty cycle/frequency and the contraction/recovery time.)

ON time (contraction) is 2-4, 5 seconds and OFF time (recovery) is 1- 0.5 second.

Programs (is to be treated)	Time (Min)		working Phase					
		t (sec.)	Pulse ON	Pulse OFF	Duty cycle %	Frequency (Hz)	Contraction time (sec.)	Recovery time (sec.)
1 Zygomatic area	2	120	6mS	44mS	12	20	4	1
2 (cheek)	2	120	2.5mS	22.5mS	10	40	4	2
3 (forehead)	2	120	3mS	9.5mS	24	80	2	1
4 (chin and jaw)	2	120	2.5mS	22.5mS	10	40	3	1
5 (eye bags)	2	120	6mS	44mS	12	20	3	1

As the data above show the similarity of the values measured., the main minor difference is because of the different shape of the voltage wave (sinusoidal/rectangular) seen on a resistive load, but as the real impedance load of the face is not resistive, but resistive/capacitive, the shape of the current becomes very similar (almost sinusoidal).
As showed by the tables, there are no new technological characteristics and no significant differences between Tua Face Fitness/Tua Trend Face device and BMR Face that could affect the safety or effectiveness of the device. Our device has been on the market in Europe since year 2002 with no adverse effect that affects the safety of the users.

10. Clinical and Non-Clinical Tests

Clinical Tests:
No new clinical studies have been submitted as part of this Premarket Notification.
Non-Clinical Tests: Tua Trend Face (Tua Face Fitness) has been designed and independently tested to the following requirements:

- IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety.
- IEC 60601-1-2 General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-10: Requirements for the safety of nerve and muscle stimulators

Also, the power supply unit complies with:

- UL 60950 - Information Technology Equipment Safety - Part 1: General Requirements
- A risk management plan was carried out per ISO 14971.
- The software is classified as a low-risk class A, as defined per the FDA guidance and the recognized ISO 62304.

11. Safety and Effectiveness

Vupiesse S.R. L complied with 21 CFR 820 and was certified by TUV Rheinland in compliance to ISO 13485 Medical Device Quality Management System for the design, manufacture, and distribution of electro-medical devices.

A risk management plan was carried out per ISO 14971.

The software is classified as a low-risk class A, per the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

12. Conclusions

Based on the preceding, Vupiesse S.R.L. Believe that Tua Face Fitness/Tua Trend Face device is substantially equivalent to the legally marketed predicate of BMR Face Device.