June 26, 2018

Infinitus (China) Company Ltd.
% Jet Li
Regulation manager
Guangzhou LETA Testing Technology Co., Ltd
6F, No.1 TianTai road, Science City, LuoGang District
Guangzhou, China

Re: K171647
Trade/Device Name: BeneLife Premium Facial Treatment Pack, Model: QZ0701A
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NFO, OHS
Dated: September 10, 2017
Received: September 19, 2017

Dear Jet Li:

This letter corrects our substantially equivalent letter of October 23, 2017.

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.

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,

William J. Heetderks -S
2018.06.26 12:48:32 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171647

Device Name
BeneLife Premium Facial Treatment Pack, Model: QZ0701A

Indications for Use *(Describe)*
The micro current stimulation mode is intended for facial stimulation and is indicated for over-the-counter cosmetic use.

The red light treatment function is intended for the treatment of periorbital wrinkles.

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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Chapter 6.510(k) Summary

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Date of the summary prepared: 2017-10-21

There is not prior submission for the device.

2. Submitter's Information

Company Name: Infinitus (China) Company Ltd.
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Application Correspondent:

Company: Guangzhou LETA Testing Technology Co., Ltd.
Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhouCity, China
Contact Person: Mr. Jet Li
Tile: Regulation Manager
Tel: +86-20-22325619
Email: med-jl@foxmail.com

3. Subject Device Information

Type of 510(k) submission: Traditional

Common Name: Transcutaneous electrical nerve stimulator for pain relief; Laser surgical instrument for use in general and plastic surgery and in dermatology.

Trade Name: BeneLife Premium Facial Treatment Pack, Model: QZ0701A

Classification Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes ; Light Based Over the Counter Wrinkle Reduction.
Review Panel: Neurology, General& Plastic Surgery

Product Code: NFO, OHS

Regulation Number: 882.5890, 878.4810

Regulation Class: 2

4. Predicate Device Information

Sponsor	Carol Cole Company (Primary Predicate Device)	Pharos Life Corporation	Nutra Luxe MD, LLC
Device Name	NUFACE® mini device	Sonilase Light Device Red	Nutra Light Red
510(k) Number	K133823	K132613	K141308
Product Code	NFO	OHS	OHS
Regulation Number	882.5890	878.4810	878.4810
Regulation Class	2	2	2

5. Device Description

The device consists of three parts: Main unit, Micro current treatment attachment and LED red light treatment attachment. There are two treatment heads for their separate treatment function. The micro current treatment attachment (electrode head) is for micro current stimulation function mode; and the LED red light attachment head is for red light irradiation function mode.

For Micro current stimulation mode:

The device has two electrode connectors for facial stimulation by applying the electrical micro current to electrodes. The output waveform is regulated Voltage of Pulsed Biphasic and provided with 5 steps of output intensity. The device is designed with 5 LED lamps of white color to indicate the output current intensity level. The micro current stimulation requires the use of a conductive gel with FDA clearance during its treatment.

For LED Red light irradiation function:

The device can provide specific photon spectrum by LED for Red irradiation mode. The red light is intended for the treatment of periorbital wrinkles. In Red irradiation mode, the device utilizes Light Emitting Diodes to provide LED light to the body. The red light output is a visible light source of high spectral purity. The output wavelength of Red light is 660 +/- 5 nm, and its power density is about 80mW/ cm2. During the treatment, the user places the treatment head to periorbital area for the treatment of periorbital wrinkle. The LED red light attachment head

includes a skin contact sensor that will not allow delivery of light when the treatment head is not contacted with the skin.

When the device is in battery charging, it cannot be operated for treatment. The device is designed with battery status indicating by five pieces of LED lamp on the front of main body of the device:

1. When the device is turned on, numbers of these LED lamps on the front of main body will display with blue color for 3 seconds to indicate the batter power level.
2. When the battery power is low, the first indicator LED lamp on the front of main body illuminates in orange color.
3. Numbers of indicator of these LED lamps will be illuminated in blue color when the battery is in charging, and the number of lamp lighting up will be increasing based on the battery power status during charging. When the battery has been charged fully, the five LED lamps is all light up,.

6. Intended Use / Indications for Use

The micro current stimulation mode is intended for facial stimulation and is indicated for over-the-counter cosmetic use.

The red light treatment function is intended for the treatment of periorbital wrinkles.

7. Test Summary

The device has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1:2005 (Third Edition)+A1:2012 and IEC 60601-2-10:2012 standards
- Electromagnetic compatibility test according to IEC 60601-1-2:2014 standard
- Photo biological safety of LED lamp systems according to IEC62471:2006
- Software verification and validation test according to the requirements of the FDA “Guidance for Pre Market Submissions and for Software Contained in Medical Devices”
- Waveform test report to verify the output specifications of the device according to IEC 60601-2-10:2012 and Guidance for Powered Muscle Stimulator.

8. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of the BeneLife Premium Facial Treatment Pack (Model: QZ0701A) is substantially equivalent to the predicate devices.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device*(Primary Predicate Device)*	Predicate Device	Predicate Device	Remark
Basic Unit Characteristics					
Device Name and Model	BeneLife Premiun Facial Treatment Pack ,Model:QZ0701A Model: EP-300	NuFACE® Mini Device	Sonilase Light Device Red	Nutra Light Red	--
510 (K) Number	Applying	K133823	K132613	K141308	--
Product Code	NFO，OHS	NFO	OHS	OHS	--
Regulation Number	882.5890， 878.4810	882.5890	878.4810	878.4810	--
Intended Use	The micro current stimulation mode is intended for facial stimulation and is indicated for over-the-counter cosmetic use. The red light treatment function is intended for the treatment of periorbital wrinkles.	The NuFACE® Mini Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use. (21 CFR 801 Subpart C). The anatomical site for application Of the NuFACE®Mini Device is the face.	The Sonlase Red OTC System is intended to be used for the treatment of used for the treatment of wrinkles, rhytides and fine linesin the periorbital region	The Nutra Light Red is a non-invasive LED light device is intended/indicated for over- the – counter use for the treatment of periorbital wrinkles, and rhytides.	SE
Apply parts	Face	Face	Face	Face	SE

Elements of Comparison	**Subject Device**	**Predicate Device*(Primary Predicate Device)***	**Predicate Device**	**Predicate Device**	**Remark**
Power Sources	3.7V 2600 mAh rechargeable lithium battery	2 rechargeable batteries	--	4 rechargeable batteries	SE Note 1
Method of Line Current Isolation	Battery Supply	Battery Supply	--	N/A	SE Note 1
For Micro current facial stimulation function					
Number of Modes for Micro current stimulation	1	1	N/A	N/A	SE
Number of Channels for Micro current stimulation	1	1	N/A	N/A	SE
-Synchronous or Alternating	N/A	Alternating	--	N/A	SE
Regulated Current or Regulated Voltage	Regulated Voltage	Regulated Voltage	N/A	N/A	SE
Software/Firmware/Microprocessor control	Yes	Yes	Yes	Yes	SE

Elements of Comparison		**Subject Device**	**Predicate Device*(Primary Predicate Device)***	**Predicate Device**	**Predicate Device**	**Remark**
Need conductive gel		Yes	Yes	NA	NA	SE
Automatic Overload Trip		Yes	Yes	--	N/A	SE
Automatic No-load Trip		Yes.	Yes	--	N/A	SE
Automatic Shut Off		Yes.	Yes	--	--	SE
Patient Override Control		Yes	Yes	--	N/A	SE
Indicator Display	On/Off Status	Yes	Yes	--	--	SE
	Low Battery	Yes	Yes	--	--	SE
	Voltage/Current Level	Yes	Yes	--	--	SE
Timer Range		Yes(Red light mode: 3 minutes, Micro current mode: 10	Yes(20 minutes)	--	3 minutes	SE Note 2

Elements of Comparison	Subject Device	Predicate Device*(Primary Predicate Device)*	Predicate Device	Predicate Device	Remark
	minutes)				
Console Weight	5 oz	6 oz	--	--	SE Note 3
Housing Materials and Construction	Console: ABS plastic	Thermoplastic	--	medical grade biocompatibility plastics via injection molding	SE
Electrode for micro current stimulation	Size of contact area: about 1.6 cm^2 Material and Geometry:Chrome plated dual electrode spheres	Size of contact area: about 1.2cm^2 Material and Geometry:Chrome plated dual electrode spheres	--	--	SE Note 3a
Micro current Output Specification					
Waveform	Pulsed Biphasic	Pulsed Monoilhasic	N/A	N/A	SE
Shape	Rectangular	Modulated Square	N/A	N/A	SE
Maximum Output Voltage (+/- 10%)	192mV @500Ω 0.778V @ 2kΩ 3.96V @ 10kΩ	222mV @500Ω 781mV @2KΩ 3.90V @10KΩ	N/A	N/A	SE Note 4

Elements of Comparison	Subject Device	Predicate Device*(Primary Predicate Device)*	Predicate Device	Predicate Device	Remark
Maximum output Current	385A µA @500Ω; 389 µA @ 2kΩ; 389 µA @10kΩ	396 µA @ 500Ω 395 µA @ 2kΩ 391µA @ 10kΩ	N/A	N/A	SE Note 4
Frequency range	8.3 Hz	8.28 Hz	N/A	N/A	SE Note 5
Pulse width range	60ms	ON phase: 60.4 ms OFF phase: 60.4 ms Total Pulse Width: 120.8ms	N/A	N/A	SE Note 5
Pulse duration	Not Multiphasic	Not Multiphasic	N/A	N/A	SE
Net Charge	0 uC @ 500Ω	1.43 uC@ 500 Ω	N/A	N/A	SE
Maximum Current Density	0.171 mA/cm²@ 500Ω	0.514 mA/cm2 @ 500 Ω	N/A	N/A	SE Note 6
Maximum Power Density	0.234 mW/cm² @ 500Ω	0.493 mW/cm² @ 500 Ω ; 1.98mW/cm² @1k Ω	N/A	N/A	SE Note 6
ON time	Constant	Constant	N/A	N/A	SE

Elements of Comparison	**Subject Device**	**Predicate Device*(Primary Predicate Device)***	**Predicate Device**	**Predicate Device**	**Remark**
OFF time	None	None	N/A	N/A	SE
For LED red light irradiation function					
LED wavelength	660±5nm	--	660nm	650 +/- 5nm	SE Note 7
LED Power Density	80mW/cm^2	--	--;	80mW/cm^2	SE
Additional Features					
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5, ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5, ISO10993-10.	SE
Electrical Safety	Comply with IEC 60601-1 and IEC 60601-2-10; IEC62471	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1	Comply with IEC 60601-1	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE

Comparison in Detail(s):

Note 1 (Power Source(s) and Method of Line Current Isolation):

The design of the power source is according to the circuit design of the device, which should ensure the safety and effectiveness. Our product complies with IEC 60601-1 requirements for electrical safety; and the performance of our device is substantially equivalent with the predicated devices under this power supply condition, which would be discussed in the follow description. Therefore, this difference on Power source and Method of Line current isolation would not introduces safety and effectiveness issue.

Note 2 (Timer Range):

The design of the timer range is basing on the intended use. The user could adjust the time by the modes based on user instruction. However, based on the output specification comparing with the predicate devices, we set the default treatment time is 10 minutes which could meet the requirements in the energy aspect. Thus, this difference on Timer range would not introduces safety and effectiveness issue on subject device.

Note 3 (Weight):

These data would be different due to different devices design because the internal circuit design and components choosing are different, which will lead to minor difference on weight or dimension. But weight and dimensions won't affect the safety and effectiveness of the device so it can deemed as the substantially equivalence.

Note 3a (Electrode):

The material of electrode is same to the ones used in K 133823，and the material of electrode of subject device had pass the testing based on ISO 10993-5 and ISO 10993-10, so there is no biocompatibility safety issue. Even there is some minor difference on the size of contact area of electrodes on the face, however, the critical parameters of micro-current output specification is same between subject device and predicate device K133823, so the minor difference do not affect the subject devices' effectiveness; and the Maximum Power Density of subject device can meet with IEC60601-2-10 and FDA guidance requirement, so we can judge that the minor difference of size of contact area do not affect the subject devices' safety and effectiveness.

Note 4 (Maximum Output Voltage and Maximum Output Current):

The effect of micro current stimulation is determined by micro-current output waveform and output current. There is only little difference between the output voltage and current of the subject device

and the predicate device. Also, the subject device and the predicate device are all compliant with IEC 60601-1, and IEC60601-2-10 and Guidance for Powered Muscle Stimulator, which means we have proved its safety as well as the effectiveness comparing with the predicate device.

Note 5 (Frequency and Pulse duration):

The effect of micro current stimulation are determined by micro-current output waveform and output current. Frequency and pulse is the time parameter of the waveform. There is only little difference between the Frequency and pulse duration of the subject device from the predicate device. Also, the subject device and the predicate device are all compliant with IEC 60601-1, and IEC60601-2-10 and Guidance for Powered Muscle Stimulator, which means we have proved its safety as well as the effectiveness comparing with the predicate device. Therefore, the subject device and predicate device are substantially equivalence on these parameters.

Note 6 (Maximum current density and Maximum power density):

The effect of micro current stimulation on facial skin are determined by micro-current output waveform and output current. There is only little difference between the output voltage and current of the subject device from the predicate device, Also, the subject device and the predicate device are all compliant with IEC 60601-1, and IEC60601-2-10 and Guidance for Powered Muscle Stimulator , and the maximum power density meet with the maximum allowed value 0.25 (W/cm^2) required in FDA guidance. Therefore, the subject device and predicate devices are substantially equivalence on these parameters.

Note 7 (LED Wavelength):

In scientific theory, the spectral range of red light wavelength is 620 – 750nm. Therefore, although there is a little difference of the LED wavelengths between the subject and predicate devices, they all belongs to the range of red light wavelengths, and the device pass the testing according to IEC62471 and IEC60601-2-57 which means the difference won't affect the effectiveness or the safety, so it can be deemed as the substantially equivalence.

Finial Conclusion:

The subject device BeneLife Premium Facial Treatment Pack (Model: QZ0701A) is Substantial Equivalence to the predicate devices.