December 20, 2017

HABALAN Med & Beauty Co., Ltd
c/o Peter Chung
President
Plus Global
300 Atwood
Pittsburgh, Pennsylvania 15213

Re: K163550
Trade/Device Name: Pobling MIITY 2
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: December 7, 2017
Received: December 13, 2017

Dear Peter Chung:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Vivek J. Pinto -S

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)*
K163550

Device Name
Pobling MIITY 2

Indications for Use *(Describe)*
The Pobling MIITY 2 is 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.

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.

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510(k) Summary

Prepared in accordance with the content and format regulatory requirements of 21 CFR Part 807.92

1. Submitter's Information

1) Name : HABALAN Med & Beauty Co., Ltd
2) Address : 907, 219, Gasandigital 1-ro, Geumcheon-gu, Seoul, KOREA
3) Contact person : Mr. Peter Chung
300 Atwood Street Pittsburgh, PA 15213, USA
Tel : 412-512-8802
4) Date prepared : December, 05, 2016

2. Device Information

1) Trade/Proprietary Name : Pobling MIITY 2
2) Common Name : Facial Toning Device
3) Classification Name : Transcutaneous Electrical Nerve Stimulator
4) Device Class : Class II
5) Product Code : NFO
6) Regulation Number : 21 CFR 882.5890

3. Predicate Device

1) Carol Cole Company, NuFACE® Plus, K103472
2) Nu Skin Enterprises, Inc., NuSkin Facial Spa, K122711

4. Intended Use

The Pobling MIITY 2 is intended for facial stimulation.

5. Indication for Use

The Pobling MIITY 2 is indicated for over-the counter cosmetic use.

6. Device Description

Pobling MIITY 2 is a facial toning device and it is composed of main unit and adaptor. The micro-current is delivered to healthy facial skin through head of main unit to stimulate the face. The device is a battery-powered and hand-held device. There have heating and cooling function by pressing the button additionally.

7 Comparison with Predicate Device

The MIITY 2 is identical with predicate devices for intended use and indications for use. It is

used as same technological principle with predicate devices to accomplish its intended use. all are hand-held, battery powered device and the there is no new questions of safety and/or effectiveness.

The determination of substantial equivalence for the MIITY2 is based on an assessment of non-clinical performance. This assessment included a comparison of the output of the MIITY2 to that of predicate. The output performance testing included:

- Maximum output voltaget
- Maximum output current

TABLE : Comparison of MIITY 2 with predicate devices

Features	Subject Device	Predicate Device		Justification
	MIITY 2	NuFACE® Plus	NuSkin Facial Spa	-
510(k) Number	To be assigned	K103472	K122711	-
Regulation Number	21 CFR § 882.5890			Same
Regulation Name	Transcutaneous Electrical Nerve Stimulator			Same
Regulatory Class	Class II			Same
Product Code	NFO			Same
Intended Use	Stimulate the face			Same
Indication for Use	Over-the-Counter Cosmetic Use			Same
Power Source	Battery operated			Same
Number output channels	1			Same
Automatic shut off	Yes			Same
Indicator Display				
1) ON / OFF?	Yes			Same
2) Low-Battery?	Yes			Same
On Time (seconds)	Constant			Same
Off Time (seconds)	None			Same
Compliance with Voluntary Standards	IEC 60601-1 / IEC 60601-1-2 / IEC 60601-1-11			Same
Mode	Two	One	One to Five	Similar
Wave form	Direct	Pulsed Monophasic	Direct Current	Same
Maximum Output Voltage	@500Ω Mode1: 174mV Mode2: 174mV	@500Ω 137mV	@500Ω Mode1: 188mV(214mV) Mode2: 189mV(225mV) Mode3: 185mV(220mV) Mode4: 184mV(212mV) Mode5: 184mV(213mV)	Similar
	@2kΩ Mode1: 710mV Mode2: 710mV	@2kΩ 769mV	@2kΩ Mode1: 722mV(1527mV) Mode2: 746mV(812mV) Mode3: 735mV(815mV) Mode4: 740mV(802mV) Mode5: 741mV(801mV)	Similar

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Features	Subject Device	Predicate Device		Justification
	MIITY 2	NuFACE® Plus	NuSkin Facial Spa	–
Maximum Output Voltage	@10kΩ Mode1: 3200mV Mode2: 3200mV	@10kΩ 3.82V	@10kΩ Mode1: 2.626V(2.978V) Mode2: 3.787V(4.011V) Mode3: 3.747V(4.014V) Mode4: 3.503V(3.980V) Mode5: 3.729V(3.980V)	Similar
Maximum Output Current	@500Ω Mode1: 350uA Mode2: 350uA	@500Ω 274uA	@500Ω Mode1: 376uA(427uA) Mode2: 379uA(449uA) Mode3: 371uA(440uA) Mode4: 368uA(424uA) Mode5: 369uA(427uA)	Similar
	@2kΩ Mode1: 360uA Mode2: 360uA	@2kΩ 387uA	@2kΩ Mode1: 361uA(763uA) Mode2: 373uA(406uA) Mode3: 367uA(407uA) Mode4: 370uA(401uA) Mode5: 370uA(400uA)	Similar
	@10kΩ Mode1: 320uA Mode2: 320uA	@10kΩ 383uA	@10kΩ Mode1: 362uA(398uA) Mode2: 379uA(401uA) Mode3: 375uA(401uA) Mode4: 350uA(398uA) Mode5: 373uA(398uA)	Similar
Heating and Cooling	Mode1: Heating (Temp. 41℃±3℃) Mode2: Cooling (Temp. 10℃±3℃)	–	–	Minor function
Weight	115g	9oz	120g (approx. 4oz)	–
Dimensions	150 x 50Ø unit : mm	3" x 5.25" x 1.25"	*Facial Spa with Large* 143 x 31.2 x 67.5 mm (5.6" x 1.2" x 2.7") *Facial Spa with Small* 136 x 31.2 x 67.5 mm (5.4" x 1.2" x 2.7")	–
Housing material and construction	ABS	Thermo Plastic	ABS, Chrome plate ABS, rubber (elastomer)	–

The heating and cooling are not a major function to be used as accomplished its intended use as stimulator. That are minor for distinguishing the mode. And also it' was also conducted the performance data. Therefore, all the difference don't affect the safety and effectiveness which is concluded after all the required testing, So no safety and effectiveness issues relating to the MIITY2

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8. Performance Data

The following performance data were provided in support of the substantial equivalence determination

1) Electrical Safety and Electromagnetic compatibility(EMC)

Electrical safety and EMC testing were conducted on MIITY2, it complies with the IEC 60601-1:2005 +am1:2002 for safety and the IEC 60601-1-2:2007 standard for EMC.

2) Biocompatibility Testing

The biocompatibility evaluation for the contact part with healthy facial skin of MIITY2 was conducted in accordance with the ISO 10993, Cytotoxicity, Skin Sensitization and Skin Irritation testing, it was considered contacting part and duration (Tissue contacting, Duration of less than 24hours)

4) Technical characteristic testing

To show the technical characteristic testing about Transcutaneous Electrical Nerve Stimulator, the test was conducted in our testing method.

5) Thermal Safety testing

The device have the heating and cooling function with stimulation. To verify the heating and cooling properties, we performed the testing in our testing method.

6) Clinical data

Not applicable

9. Conclusion

The fundamental technology to be accomplished its intended use in view of technological and operational characteristics between MIITY2 and predicate device is same. Non-clinical performance as documented support the safety and effectiveness are similar to the predicate device.

In other words, the MIITY2 is substantially equivalent to the predicate devices.