June 3, 2026

Touchbeauty Beauty & Health (Shenzhen) Co., Ltd.
% Bing Huang
RA Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm.2401 Zhenye International Business Center, # 3101-90
Qianhai Rd.
Shenzhen, Guangdong 518052
China

Re: K260179
Trade/Device Name: VITA Multi-Function Head Brush (TB-2343F, TB-2442F)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: May 8, 2026
Received: May 8, 2026

Dear Bing Huang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260179

Please provide the device trade name(s).

VITA Multi-Function Head Brush (TB-2343F, TB-2442F)

Please provide your Indications for Use below.

VITA Multi-Function Head Brush is an Over-The-Counter (OTC) device.
Micro-current function: The micro current stimulation mode is intended for facial stimulation and is indicated for over-the counter cosmetic use.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary
K260179

Date: 2026-06-03

I. Submitter

TOUCHBEAUTY BEAUTY & HEALTH (SHENZHEN) CO., LTD.
29/F, Block B, Tiley Central Plaza, No.195 Haide 3rd Road, Nanshan District, Shenzhen, China.
Post code: 518064
Tel.: +86 400-1191-180

Zhou Elin
Title: CEO
Tel.: +86 755 3366 2222 ext.666
Email: chow@touchbeauty.com

II. Device

Name of Device: VITA Multi-Function Head Brush
Model(s): TB-2343F, TB-2442F
Common or Usual Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Classification Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NFO
Regulation Number: 21CRF 882.5890

Note: The device function-under-review in this 510(k) is transcutaneous microcurrent electrical stimulation for aesthetic purposes, which falls under the NFO product code under the regulation 21 CRF 882.5890. Only this specific device function was cleared in this 510(k).

III. Predicate Device

Manufacturer	Predicate Device	510(k) Number	Cleared Date
XTREEM PULSE LLC	PureLift Pro Plus	K221443	October 21, 2022
BELEGA Co., Ltd.	Beagank 4T Plus	K233010	November 21, 2023
Carol Cole Company	NuFACE Mini Device	K133823	Apr 17, 2014

IV. Device Description

The VITA Multi-Function Head Brush is a hand-held device. It consists of a host, a removable treatment head, and a charging cable. The host has a button, indicator lights, and the device's power-

on/off, treatment mode switch can be achieved by pressing the button. The removable treatment head has lights row, stainless steel bristles.
The device generates a micro-currents on the stainless steel bristles which will applied on the facial skin for facial stimulation.
The device will automatically shut down after each mode completes treatment within 10 minutes. The device is powered by a built-in rechargeable lithium battery.

V. Indications for Use

VITA Multi-Function Head Brush is an Over-The-Counter (OTC) device.
Micro-current function: The micro current stimulation mode is intended for facial stimulation and is indicated for over-the counter cosmetic use.

VI. Comparison of Technological Characteristics With the Predicate Device

VITA Multi-Function Head Brush is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance:

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Predicate Device 2**	**Predicate Device 3**	**Remark**
510(k) Number	Pending	K221443	K233010	K133823	/
Trade name	VITA Multi-Function Head Brush (Model(s): TB-2343F, TB-2442F)	PureLift Pro Plus	Beagank 4T Plus	NuFACE Mini Device	/
Manufacturer	TOUCHBEAUTY BEAUTY & HEALTH (SHENZHEN) CO., LTD	XTREEM PULSE LLC	BELEGA Co., Ltd.	Carol Cole Company	/
Regulation number	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890	Same
Product code	NFO	NFO	NFO	NFO	Same
Device classification	II	II	II	II	Same
Prescription or OTC	OTC	OTC	OTC	OTC	Same
Indication for use/ Intended use	VITA Multi-Function Head Brush is an Over-the-Counter (OTC) device. Face Mode: Micro-current function: The micro current stimulation mode is intended for facial stimulation and is indicated for over-the counter cosmetic use.	Intended for facial stimulation and indicated for over-the-counter cosmetic use.	The BEAGANK 4T PLUS is a handheld portable device for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation.	The NuFACE Mini Facial Toning device is intended for facial stimulation and is indicated oor over-the-counter cosmetic use (21 CFR 807 Subpart C)。	Same
Handheld or stationary	Hand-held Type	Hand-held Type	Hand-held Type	Hand-held Type	Same
Treatment area	Face	Face	Face and neck or body	Face	Same
Number of out channels	1 output channel	1 output channel	1	1	Same

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Predicate Device 2**	**Predicate Device 3**	**Remark**
Regulated current or regulated voltage	Voltage	Regulated current	Voltage	Both	Same
Software/ Firmware/ Microprocessor Control	Yes	Yes	Yes	Yes	Same
Indicator Display	Yes	Yes	Unknown	Yes	Same
Timer range	10 minutes a time	10 minutes only	Maximum 5 minutes	21 minutes	Same as the primary
Type of protection	Type BF	Type BF	Type BF	Unknown	Same
On/off status	Yes	Yes	Yes	Yes	Same
Waveform	Pulses Monophasic	Pulses Monophasic, alternating polarity	Rectangle, biphasic asymmetric	Pulsed Monophasic	Same The waveform of subject device is the same as predicate device 3.
Shape	Rectangular Pulses	Rectangular Pulses	Rectangle, biphasic asymmetric	Modulated Square	Same
Maximum output voltage	20Vpp @500Ω 32Vpp @ 2kΩ 44Vpp @ 10kΩ	20Vpp(@500Ω) 32Vpp(@2kΩ) 44Vpp(@10kΩ)	Mode 1: 127mV (0.12V)@500Ω 515mV (0.51V)@2KΩ 1.83V@10KΩ	Specify units: 222mV @500Ω 781mV @ 2kΩ 3.90V @ 10kΩ	Same

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Predicate Device 2**	**Predicate Device 3**	**Remark**
			Mode 2: 110mV(0.11V)@500Ω 507mV(0.50V)@2KΩ 1.87V@10KΩ Mode 3: 16.6V@500Ω 21.0V@2KΩ 22.5V@10KΩ Mode 4: 15.3V@500Ω 21.2V@2KΩ 22.9V@10KΩ		
Maximum output current	2.96mA$_{r.m.s}$ @500Ω 1.35mA$_{r.m.s}$ @ 2kΩ 0.515mA$_{r.m.s}$@10kΩ	9mA(@500Ω) 4.4mA(@2kΩ) 1.2mA(@10kΩ)	Mode 1: 0.19mA@500Ω 0.18mA@2KΩ 0.16mA@10KΩ Mode 2: 0.45mA@500Ω 0.39mA@2KΩ 0.24mA@10KΩ Mode 3:	396μA @500Ω 395μA@ 2kΩ 391μA@ 10kΩ	**Similar Note 1**

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Predicate Device 2**	**Predicate Device 3**	**Remark**
			30.8mA@500Ω 8.52mA@2KΩ 2.26mA@10KΩ Mode 4: 31.4mA@500Ω 8.60mA@2KΩ 2.15mA@10KΩ		
Pulse width	4μs	4μs	Mode 1: 130μs Mode 2: 130μs Mode 3: 80μs Mode 4: 92μs	Specify unites ON Phase: 60.4ms OFF phase: 60.4ms Total Pulse Width: 120.8ms	Same
Frequency (Hz)	1.6kHz	1.37kHz～1.73kHz	Mode 1: 3.80kHz Mode 2: 3.80kHz Mode 3: 3.65kHz Mode 4: 1.64kHz	8.28Hz	**Similar Note 2**
Symmetrical phases	Not multiphasic	Not multiphasic	No	Not Multiphasic	Same
Net charge (μC per pulse train)	0.16μC	0μC per pulse train	Mode 1: 0.025μC@500Ω Mode 2: 0.025μC@500Ω Mode 3: -1.3μC@500Ω Mode 4: 0μC@500Ω	1.43μC	**Different Note 3**

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Predicate Device 2**	**Predicate Device 3**	**Remark**
Maximum phase charge (μC)	0.2304μC	5.81μC@500Ω	Mode1: 0.059μC@500Ω Mode 2: 0.025μC@500Ω Mode 3: 2.2μC@500Ω Mode 4: 0.29μC@500Ω	23.7μC	**Different Note 3**
Maximum current density (mA/cm^2)	1.62mA/cm^2	8.8mA/cm^2@500Ω	With a wet cotton pad (Purified water) Mode 1: 0.15~1.36mA/cm^2@500Ω Mode 2: 0.10~0.92mA/cm^2@500Ω Mode 3: 4.26~38.43mA/cm^2@500Ω Mode 4: 3.13~28.21mA/cm^2@500Ω	0.514mA/cm^2	**Similar Note 4**
Maximum power density	2394μW/cm^2	39600μW/cm^2	With a wet cotton pad: Mode 1: 11.39μW/cm^2@500Ω Mode 2: 33.87μW/cm^2@500Ω Mode 3: 1124.0μW/cm^2@500Ω Mode 4: 556.96μW/cm^2@500Ω	1981μW//cm^2	**Different Note 4**

Comparison Elements	Subject Device	Primary Predicate Device	Predicate Device 2	Predicate Device 3	Remark
Main Materials	Enclosure: ABS; Stainless Steel Bristles Button: Stainless;	Not publicly available	ABS	Thermo Plastic	Different, but solved by biocompatibility tests
Electrical safety	IEC 60601-1 IEC 60601-1-11 IEC 60601-1-2 IEC 60601-2-10 IEC 62133-2	ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Same
Biocompatibility feature	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10 and ISO 10993-23	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10 ISO 10993-23	Not publicly available	Same

Note 1:
The maximum output voltage of the subject device is same as the primary predicate device(K221443). The maximum output current seems to be different from the predicate devices, but it is within the range of the predicate devices. Besides, the device has been tested for electrical safety as per IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-10 requirements, so this difference does not impact its safety and effectiveness.

Note 2:
Though the Frequency of the subject device is a little different from the primary predicate device, it is within the rang of the primary predicate device. So this difference will not raise any safety or effectiveness issues.

Note 3:
Though Maximum phase charge of the subject device is a little different from the primary predicate device, it is within the rang of the primary predicate device and secondary predicate device. So this difference will not raise any safety or effectiveness issues.
The waveform of the subject device is the same as the predicate device 3, both are Pulsed Monophasic. And the net charge (0.16μC) of the subject device, which is much lower than the requirement in clause 8.4.3 of IEC 60601-1 that the shored charge should not exceed 45μC, is much smaller than that of the predicate device 3 (1.43μC), as well as that of the mode 3 of the predicate device 2 (-1.3μC). Besides, the subject device has been tested for electrical safety as per IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-10 requirements, so this difference does not impact its safety and

effectiveness. Therefore, the waveform and net charge of the subject device will not increase the risk of charge accumulation at the electrode-skin interface.

Note 4:

Though the Maximum current density and Maximum power density of the subject device is a little different from the primary predicate device, it is within the rang of the primary predicate device and secondary predicate device, and the 1.62mA/cm² is less then the limit of 2mA/cm2 specified in IEC 60601-2-10. The subject device has provided adequate electrical safety and performance testings, which were conducted according to applicable standards for nerve and muscle stimulators (including IEC 60601-1 and IEC 60601-2-10) as well as lab bench performance evaluation. So this difference will not raise any safety or effectiveness issues.

VII.Performance Data

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

1) Biocompatibility Safety

The materials of the patient-directly contacting components of the subject device is performed the biocompatibility evaluation in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on September 4, 2020", as recommended by FDA. The following testing was performed to, and passed, including:

- ISO 10993-5: 2009, Biological evaluation of medical devices –Par t 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23: 2021, Biological evaluation of medical devices - Part 23: Tests for irritation

2) Electrical Safety and EMC Safety

Electrical safety and Eye safety testing was performed to, and passed, the following standards:

- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Medical Electrical Equipment –Part 1: General Requirements for Basic Safety and Essential Performance –Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- IEC 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 62133-2 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems.

3) Software Verification and Validation

Software documentation consistent with ***Basic Documentation*** of concern was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

Summary

Based on the above performance as documented in this application, the subject device was found to have a safety and effectiveness profile that is similar to the predicate devices.

VIII. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, it can be concluded that the

VITA Multi-Function Head Brush is as safe, as effective, and performs as well as the legally marketed predicate devices.