October 27, 2025

Touchbeauty Beauty & Health (Shenzhen) Co., Ltd
% Bing Huang
RA Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center
No. 3101-90, Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K252053
Trade/Device Name: VITA Multi-Function Head Brush (TB-2443F, TB-2442AF, TB-2343F, TB-2442F)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: OHS, OLP, OAP, ISA
Dated: July 1, 2025
Received: July 1, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2025.10.27 21:28:32 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252053

Device Name
VITA Multi-Function Head Brush Model(s): TB-2443F, TB-2442AF, TB-2343F, TB2442F

Indications for Use *(Describe)*
VITA Multi-Function Head Brush is an Over-The-Counter (OTC) device.

Head Mode: The device is indicated to promote hair growth in male with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V and females with androgenic aplopecia who have Ludwig-Savin Classification of I-4, II-1, II-2, or frontal and both with Fitzpatrick Skin Phototypes I-IV.

Face Mode:
LED therapy function: The device is indicated for the treatment of full face wrinkles and/or mild to moderate inflammatory acne.

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

"510(k) Summary" as required by 21 CFR Part 807.92.

K252053

Date: 2025-10-27

I. Submitter

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II. Device

Name of Device: VITA Multi-Function Head Brush
Model(s): :TB-2443F, TB-2442AF, TB-2343F, TB2442F
Common or Usual Name: Light Based Over The Counter Wrinkle Reduction(OHS)
Over-The-Counter Powered Light Based For Acne(OLP)
Laser, Comb, Hair (OAP)
Therapeutic electric massager(ISA)
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology(OHS, OLP, OAP)
Massager, Therapeutic, Electric(ISA)
Regulatory Class: II
Product Code: OHS, OLP, OAP, ISA
Regulation Number: 21 CFR 878.4810; 21CRF 890.5500; 890.5660

III. Predicate Device & Reference Device

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Cleared Date
YIBIN YINGTONG INTELLIGENT TECHNOLOGY CO.,LTD.	Intelligence LaserComb (YTLC001-W)	K213789	June 24, 2022
Light Tree Ventures Europe B.V.	Aduro Comb (Model: SZ-22A)	K230597	April 28, 2023
Galactic Beauty, LLC	MMSphere™	K190443	June 24, 2019

Reference device:

Manufacturer	Predicate Device	510(k) Number	Cleared Date
Shenzhen Sungrow LED Technology Co.,Ltd	LED Light Therapy Mask (Models:G15, G15P, G15K, G11P, G11, G10, G13, G14, G17, VISO, PRANA, Chin2Chest, BBL-FACEMASK)	K250830	June 9, 2025

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 and liquid reservoir (applicable for model TB-2443F/ TB-2442AF), of which the liquid reservoir is used for the hair care after treatment.
The LEDs and low-level lasers in the removable treatment head emit light on the treatment area.In addition, the device is also equipped with a built-in micro motor to generates micro-vibration to relax the facial skin. The device has a head mode and face mode, and 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.
Head Mode: The device is indicated to promote hair growth in male with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V and females with androgenic aplopecia who have Ludwig-Savin Classification of I-4, II-1, II-2, or frontal and both with Fitzpatrick Skin Phototypes I-IV. Face Mode:
LED therapy function: The device is indicated for the treatment of full face wrinkles and/or mild to moderate inflammatory acne.

VI. Comparison of Technological Characteristics With the Predicate Device

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

Table 1: Comparison between subject device and the FDA cleared OAP device.

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
510(k) Number	K252053	K213789	K230597	/
Trade name	VITA Multi-Function Head Brush (Model(s): TB-2443F, TB-2442AF, TB-2343F, TB-2442F)	Intelligence LaserComb (YTLC001-W)	Aduro Comb (Model: SZ-22A)	/
Product code	OAP	OAP	OAP	Same
Device classification	II	II	II	Same
Prescription or OTC	OTC	OTC	OTC	Same
Indication for use/ Intended use	VITA Multi-Function Head Brush is an Over-the-Counter (OTC) device. Head Mode: The device is indicated to promote hair growth in male with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V and females with androgenic aplopecia who have Ludwig-Savin Classification of I-4, II-1, II-2, or frontal and both with Fitzpatrick Skin Phototypes I-IV.	The Intelligence LaserComb (Model: YTLC001-W) is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenic alopecia who have Ludw ig-Savin Classif ications of I-4, II-1, II-2, or frontal and both with Fitzpatrick Skin Phototypes I-IV.	The Aduro Comb (Model: SZ-22A) is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood- Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I-IV.	Same
Type of Laser	Low-level laser diodes and light emitting diodes	Visible red light-emitting diodes	Light emitting diodes	Same
Wavelength	Laser: 650nm±10nm Red light LED: 660nm±10nm	655nm±10nm	650±10nm	Same
Amounts of laser	Laser: 8pcs Red light LED: 12pcs	10	22 LEDs	Similar
Energy of Per Laser Diode	≤5mW	≤5mW	Unknown	Same

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
Power Intensity	3.0mW/cm^2	2.5 mW/cm^2	2.77 mW/cm^2	Similar
Dosage Intensity	Laser:1.8J/cm^2	1.2 J/cm^2	4.98 J/ cm^2	Similar
Treatment Time	10 minutes per treatment	8 minutes per treatment	Each Treatment: 30 min	Same
Treatment Frequency	3 times per week	3 times per week (every other day)	every other day, for 16 weeks	Same
Applicable People	Norwood-Hamilton IIa-V (males) Ludw ig-Savin I-4, II-1, II-2, or f rontal (females)	Norwood-Hamilton IIa-V (males) Ludw ig-Savin I-4, II-1, II-2, or f rontal (females)	Norwood-Hamilton IIa-V (males) Ludw ig-Savin I-4, II-1, II-2, or f rontal (females)	Same
Applicable Skin	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV	Same
Appearance Design	Comb	Comb	Comb	Same

Table 2: Comparison between subject device and the FDA cleared OHS and OLP device.

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Reference Device 1**	**Remark**
510(k) Number	K252053	K190443	K250830	/
Trade name	VITA Multi-Function Head Brush (Model(s): TB-2443F, TB-2442AF, TB-2343F, TB-2442F)	MMSphere ™	LED Light Therapy Mask (Models:G15, G15P, G15K, G11P, G11, G10, G13, G14, G17, VISO, PRANA, Chin2Chest, BBL-FACEMASK)	/
Product code	OHS, OLP	OHS, OLP	OHS, OLP	Same
Device classification	II	II	II	Same
Prescription or OTC	OTC	OTC	OTC	Same
Indication for use/ Intended use	VITA Multi-Function Head Brush is an Over-the-Counter (OTC) device.	MMSphereTM Light Therapy Device emits energy in the red, blue and amber regions of the spectrum, specifically	Red light: Treatment of full-face wrinkles. Yellow light: Treatment of full-face wrinkles. Red+Infrared light:	Same

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Reference Device 1**	**Remark**
	Face mode: LED therapy function: The device is indicated for the treatment of full face wrinkles and/or mild to moderate inflammatory acne.	indicated to treat wrinkles and/or mild to moderate acne. The MMSphereTM is designed to be used for 20 minute treatments three to seven times per week.	Treatment of full-face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne. Mixed light (Red+Blue+Infrared): Treatment of mild to moderate inflammatory acne.	
Handheld or stationary	Hand-held Type	Both	Mask	Same
Irradiance source	LEDs	LEDs	LEDs	
Anatomical sites	Entire Face	Entire Face	Whole face	
Wavelength	660nm+/-10nm 465nm+/-10nm	605nm 625nm 465nm	Blue: 415 nm+/-10nm Red: 660 nm+/-10nm Yellow: 590nm+/-10nm Near-Infrared: 850nm+/-10nm	Same
Power Intensity	Red: 2.9mW/cm ^{2} Blue:2.8mW/cm ^{2}	Red 2.45mW/cm ^{2} Blue 1.33mW/cm ^{2}	Mode 1: Red:15-22 Mode 2: Yellow: 20-30 Mode 3: Red-near infrared: 20-30 Mode 4: Blue-red-near infrared: 25-45 Mode 5: Blue: 13-23 Mode 6: Yellow: 20-30, red-near infrared: 20-30, blue: 13-23	Similar

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 60601-1-2:2014 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- IEC 60601-1:2005 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015 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 60601-2-83:2019 Medical Electrical Equipment - Part 2-83: Particular Requirements For The Basic Safety And Essential Performance Of Home Light Therapy Equipment
- IEC 62133-2:2017 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.
- IEC 602825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements.

3) Eye Safety

- IEC 62471:2006 Photobiological safety of lamps and lamp systems

4) 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.