



October 17, 2025

Shenzhen Qianyu Technology Co., Ltd.  
% Tangyao Dai  
RA Specialist  
Feiyong Drug & Medical Consulting Technical Service Group  
Rm 2401 Zhenye International Business Center  
No. 3101-90, Qianhai Road  
Shenzhen, Guangdong 518000  
China

Re: K250227

Trade/Device Name: JOVS Electric Stimulation Beauty Device (JE2)  
Regulation Number: 21 CFR 882.5890  
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief  
Regulatory Class: Class II  
Product Code: NFO  
Dated: January 24, 2025  
Received: January 27, 2025

Dear Tangyao Dai:

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](mailto: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  
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Physical Medicine Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K250227

Device Name

JOVS Electric Stimulation Beauty Device (JE2)

Indications for Use (Describe)

JOVS Electric Stimulation Beauty Device is indicated for over-the-counter aesthetic use including facial and neck stimulation.

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

## K250227

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

### I. Submitter

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Contact person: Guoyang Li

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Date: 2025-10-8

### II. Subject Device

Name of Device: JOVS Electric Stimulation Beauty Device

Model(s): JE2

Common or Usual Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes

Regulation Name: Transcutaneous electrical nerve stimulator for pain relief

Regulatory Class: II

Product Code: NFO

Regulation Number: 21 CFR 882.5890

### III. Predicate and Reference Device

#### ➤ Predicate devices

No.	Manufacturer	Device name	Product code	510(k) Number	Cleared Date
1.	Belega Inc.	Beagank 4T Plus	NFO	K233010	2023.11.21
2.	BIO-MEDICAL RESEARCH, LTD.	BMR Face	NFO	K103031	2011.11.10
3.	SALTON, INC.	Rejuvenique System Model: RJV-10	NFO, GYB	K011935	2021.08.08

#### ➤ Reference device

No.	Manufacturer	Device name	Product code	510(k) Number	Cleared Date
1	Raja Trading Company, Inc.	MyoLight Microcurrent Handpiece	NFO	K243063	2025.02.10

#### **IV. Device Description**

The JOVS Electric Stimulation Beauty Device is a portable, non-sterile, reusable device designed to achieve the aesthetic effect. It mainly consists of main unit, charging and disinfection base, and power cable. The device is supplied by internal rechargeable lithium battery, which can be recharged by external charger through the Type-C charging cable. The device is un-usable when charging.

The device is only home environment use, which has the spring electrode head (electric stimulation) to provide the following function:

The JOVS Electric Stimulation Beauty Device is indicated for over-the-counter aesthetic use including facial and neck stimulation.

#### **V. Indications for Use**

JOVS Electric Stimulation Beauty Device is indicated for over-the-counter aesthetic use including facial and neck stimulation.

#### **VI. Comparison of Technological Characteristics With the Predicate Device**

The JOVS Electric Stimulation Beauty Device has the same intended use as the predicates. The technological characteristics, features, specifications, materials are similar to the predicate devices and reference device. Any minor differences between the subject device and the listed predicate devices and reference device do not raise any issues of safety or effectiveness. Performance data supports that the device is safe and as effective as the predicate devices and reference device for its intended use.

Therefore, the JOVS Electric Stimulation Beauty Device may be found substantially equivalent to its predicate devices and reference device.

<u>Elements of Comparison</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>	<u>Reference Device 1</u>	<u>Remark</u>
Device Name and Model	JOVS Electric Stimulation Beauty Device Model: JE2	BEAGANK 4T PLUS	BMR Face	Rejuvenique System Model: RJV-10	MyoLight Microcurrent Handpiece	/
510(k) Number	K250227	K233010	K103031	K011935	K243063	/
Regulation number	882.5890	882.5890	882.5890	882.5890, 882.1275	882.5890	Same
Product code	NFO	NFO	NFO	NFO, GYB	NFO	Same
Device classification	Class II	Class II	Class II	Class II	Class II	Same
OTC prescription or	OTC	OTC	OTC	OTC	Prescription	Same
Indications for use	JOVS Electric Stimulation Beauty Device is indicated for over-the-counter aesthetic use including facial and neck stimulation.	The BEAGANK 4T PLUS is a handheld portable device for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation.	BMR Face is intended for facial stimulation and is indicated for Over the Counter Cosmetic Use.	The Rejuvenique System is indicated for cosmetic use.	The device is indicated for aesthetic use including facial and neck or body skin stimulation.	Different. Compared to the predicate devices, the subject device is limited to use on the facial and neck areas. Both the subject and predicate devices use the same fundamental electrical stimulation technology and are intended for

<u>Elements of Comparison</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>	<u>Reference Device 1</u>	<u>Remark</u>
						overlapping treatment areas and patient populations. Therefore, the difference in the indications for use does not impact the device's safety or effectiveness.
Dimensions	202×33×66mm	Not publicly available	6.0x8.0x2.1(cm)	4-1/2"×3"×1-1/4 (inch)	Handpiece #1: 62mm x 147 mm Handpiece #2: 39mm x 139.5 mm	Different. The dimensions and weight of the subject device are different from the predicate devices, however this difference is insignificant and do not impact its safety and effectiveness.
Weight	634g	136g	63g	80 grams	Handpiece #1: 1100 g Handpiece #2: 720 g	
Treatment area	Face and neck	Face, neck and body	Facial skin	Facial skin	Face, neck and body	Same
Power source	Adapter input: 5V=1A Battery voltage: DC3.7V, 1000mAh	Internal rechargeable Lithium-ion battery	3.6V rechargeable batteries	Single 9V battery	Mains Power 110-120, 220 - 240 VAC, 50- 60 Hz	Different. Although the power source is different from the predicate devices, the lithium battery of the subject device

<u>Elements of Comparison</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>	<u>Reference Device 1</u>	<u>Remark</u>
						complies with the IEC 62133-2 standard, and 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.
Number of output modes	2	4	3	1	1	Different. Although the number of output modes is different from that of the predicate devices, the output parameters of each mode have been tested, and the subject device has passed IEC 60601-1 and IEC 60601-2-10, so this difference does not impact its safety and effectiveness.
Number of output channel	1	1	2	1	Not publicly available	Same
Regulated Current	Regulated voltage	Regulated voltage	Not publicly available	Regulated voltage	Regulated voltage	Same

<u>Elements of Comparison</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>	<u>Reference Device 1</u>	<u>Remark</u>
or Regulated Voltage?						
Software/ firmware/ microprocessor control	YES	YES	YES	YES	YES	Same
Automatic Overload Trip?	NO	Not required due to circuit design	Not publicly available	NO	Not publicly available	Same
Automatic No-Load Trip?	NO	Not required due to circuit design	Not publicly available	NO	Not publicly available	Same
Automatic Shut Off?	YES	YES	Not publicly available	YES	YES	Same
Patient Override Control?	YES	YES	Not publicly available	YES	Not publicly available	Same
Indicator Display: - On/Off Status? - Low Battery? - Voltage/ Current Level?	YES	YES	YES	YES	Not publicly available	Same

<u>Elements of Comparison</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>	<u>Reference Device 1</u>	<u>Remark</u>
Timer Range	5 minutes	Max 5 minutes	10/15/20minutes	16 minutes	20 Minutes Recommended Treatment Time	Similar
Compliance with Voluntary Standards?	ISO 10993-5 ISO 10993-10 ISO 10993-23 IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	IEC 60601-1 IEC 60601-1-2	ISO 10993-5 ISO 10993-10 IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Not publicly available	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 ISO 14971 IEC 62366	Similar
Compliance with 21 CFR 898?	YES	YES	YES	YES	YES	Same
Housing materials	PC+ABS+PVC+Stainless steel	ABS	Plastic case built of abs, electrodes of skin conductive through adhesive hydrogel layer.	Not publicly available	Molded PC-ABS plastic material with screw assembly construction.	Different. Although the materials of the subject device are not entirely the same as the predicate devices, the subject device has been tested for

<u>Elements of Comparison</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>	<u>Reference Device 1</u>	<u>Remark</u>
						biocompatibility as per ISO 10993 series standards, so this difference does not impact its safety and effectiveness.
<b>Output specifications</b>						
Waveform Type	Pulsed biphasic, square wave	Rectangle, biphasic asymmetric	Symmetric, pulsed, biphasic	Pulsed biphasic, Rectangular (+phase), Spike (-phase)	Pulsed Biphasic rectangular modulated by trapezoidal	Same
Maximum Output Voltage	(+/-10%) 27V@500Ω 35.5V@2kΩ 36.7V@10kΩ	(+/-15%) Mode 1: 0.12V@500Ω 0.51V@2KΩ 1.83V@10KΩ Mode 2: 0.11V@500Ω	15 V±10% @ 500 Ω 60 V±10% @ 2K Ω 32 V±10% @ 10K Ω	(+/-10%) 18.8V@ 500Ω 24.8V@ 2kΩ 28.0V@ 10kΩ	(+/-20%) 30V @ 500 Ω 33V @ 1,000 Ω 35V @ 10,000 Ω	Different. The “Maximum Output Voltage” and “Maximum Output Current” of the subject device are very similar to that of the predicate device 2 and basically within the range of the predicate device 2 and reference device

<u>Elements of Comparison</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>	<u>Reference Device 1</u>	<u>Remark</u>
		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				1. And we have tested the product waveform parameters according to FDA guidance documents and tested the device according to the requirements of IEC 60601-2-10, the tests are all passed, so these differences do not impact its safety and effectiveness.
Maximum Output Current	(+/-10%) 54mA@500Ω 17.75mA@2KΩ 3.67mA@10KΩ	Mode 1: 0.19mA@500Ω 0.18mA@2KΩ 0.16mA@10KΩ	30mA±10%@500Ω 30mA±10%@2KΩ 3.2mA±10%@10KΩ	(+/-10%) 37.6mA @ 500Ω 12.4mA @ 2kΩ 2.8mA@ 10kΩ	60mA @ 500 Ω 33mA @ 1000 Ω 3.5mA @ 10,000 Ω	

<u>Elements of Comparison</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>	<u>Reference Device 1</u>	<u>Remark</u>
		Mode 2: 0.45mA@500Ω 0.39mA@2KΩ 0.24mA@10KΩ  Mode 3: 30.8mA@500Ω 8.52mA@2KΩ 2.26mA@10KΩ  Mode 4: 31.4mA@500Ω 8.60mA@2KΩ 2.15mA@10KΩ				
Pulse Width	110μs ± 20%	Mode 1: 265μs Mode 2: 265μs Mode 3: 274μs Mode 4: 610μs	160-200μs	300ms fixed	128μs, 256μs, 384μs	Different. The pulse width of the subject device is similar to that of the predicate device 1 and reference device 1. And we have tested

<u>Elements of Comparison</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>	<u>Reference Device 1</u>	<u>Remark</u>
						the product waveform parameters according to FDA guidance documents and tested the device according to the requirements of IEC 60601-2-10, the tests are all passed, so these differences do not impact its safety and effectiveness.
Output Frequency	2.5kHz ± 20%	Mode 1: 3.80kHz Mode 2: 3.80kHz Mode 3: 3.65kHz Mode 4: 1.64kHz	70-80Hz	8 Hz fixed	1 ~ 63 Hz	Different. The output frequency of the subject device is within the range of that of the primary predicate device. And we have tested the product waveform parameters according to FDA guidance documents and tested the device according to the requirements of IEC 60601-2-10, the tests are all passed, so these differences do

<u>Elements of Comparison</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>	<u>Reference Device 1</u>	<u>Remark</u>
						not impact its safety and effectiveness.
Net charge	0 $\mu$ C@500 $\Omega$	Mode 1: 0.025 $\mu$ C@500 $\Omega$ Mode 2: 0.025 $\mu$ C@500 $\Omega$ Mode 3: -1.3 $\mu$ C@500 $\Omega$ Mode 4: 0 $\mu$ C@500 $\Omega$	0 $\mu$ C@500 $\Omega$	0 $\mu$ C@500 $\Omega$	0 $\mu$ C (Pulse is biphasic symmetrical)	Same
Maximum phase charge	7.19 $\mu$ C@500 $\Omega$	Mode1: 0.059 $\mu$ C@500 $\Omega$ Mode 2: 0.025 $\mu$ C@500 $\Omega$ Mode 3: 2.2 $\mu$ C@500 $\Omega$ Mode 4: 0.29 $\mu$ C@500 $\Omega$	Not publicly available	11.3mC@500 $\Omega$	23 $\mu$ C	Different. The maximum phase charge and maximum current density of the subject device are within the range of that of the primary predicate device and predicate device 2. The maximum power density of the subject device are within the range of that of the predicate device 1 and predicate device 2. And we have tested the product waveform
Maximum Current Density	12.56mA/cm <sup>2</sup> @500 $\Omega$	Mode 1: 0.15~1.36mA/cm <sup>2</sup> @500 $\Omega$ Mode 2: 0.10~3.21mA/cm <sup>2</sup> @500 $\Omega$ Mode 3: 4.26~220mA/cm <sup>2</sup> @500 $\Omega$ Mode 4: 3.13~224.3mA/cm <sup>2</sup> @500 $\Omega$	1mA/cm <sup>2</sup> @500 $\Omega$	46.4mA/cm <sup>2</sup> @500 $\Omega$	82 $\mu$ A/mm <sup>2</sup>	

<u>Elements of Comparison</u>	<u>Subject Device</u>	<u>Primary Predicate Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>	<u>Reference Device 1</u>	<u>Remark</u>
Maximum Power Density	0.178W/cm <sup>2</sup> @500Ω	Mode 1: 8.51~11.39μW/cm <sup>2</sup> @500Ω  Mode 2: 17.46~33.87μW/cm <sup>2</sup> @500Ω  Mode 3: 1.124~106.6mW/cm <sup>2</sup> @500Ω  Mode 4: 0.56~51.78mW/cm <sup>2</sup> @500Ω	3.91W/cm <sup>2</sup> @500Ω	2.31mW/cm <sup>2</sup> @500Ω	0.012W/ cm <sup>2</sup>	parameters according to FDA guidance documents and tested the device according to the requirements of IEC 60601-2-10, the tests are all passed, so these differences do not impact its safety and effectiveness.

## **VII. Performance Data**

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

### **1) Biocompatibility Testing**

The biocompatibility evaluation for the body-contacting components of the JOVS Electric Stimulation Beauty Device was conducted 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 recognized by FDA. The following testing was performed to, and passed, including:

- ISO 10993-5: 2009, Biological evaluation of medical devices –Part 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**

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11 Medical Electrical Equipment –Part 1-11: 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 Level* 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.

### **4) Performance test**

The waveform test report has been conducted to verify the output specifications of the device according to Guidance for Powered Muscle Stimulator 510(k)s.

## **VIII. Conclusions**

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device is as safe, as effective, and performs as well as the legally marketed predicate devices.