July 23, 2026

Shenzhen Kaiyan Medical Equipment Co., Ltd.
Alain Dijkstra
CEO
Bldg.#3 and Bldg.#5, 40th Of Fuxin St.
Huaide Community Fuyong Town
Shenzhen, Guangdong 518103
China

Re: K253932
Trade/Device Name: FACEGYM Pro Device (HD-109)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: June 22, 2026
Received: June 22, 2026

Dear Alain Dijkstra:

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.	K253932

Please provide the device trade name(s).

FACEGYM Pro Device (HD-109)

Please provide your Indications for Use below.

The FACEGYM Pro Device (Model: HD-109) is intended for facial and neck 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)

K253932
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. Submitter's Information

Sponsor Name: Shenzhen Kaiyan Medical Equipment Co., Ltd
Establishment Registration Number: 3011644607
Address: Building#3 and Building#5, 40th of Fuxin Street, Huaide Community Fuyong Town, Baoan District, Shenzhen, Guangdong 518103, China
Contact Person (including title): Alain Dijkstra (Manager)
Tel: +86-135-10378748
Fax: +86-755-25024651
E-mail: registrar01@kaiyanmedical.com

Distributor:
Company: FaceGym Ltd.
Address: 6th Floor 1-4 Argyll Street, London, England, W1F 7TA.

2. Subject Device Information:

Trade Name: FACEGYM Pro Device
Classification Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Review Panel: Neurology
Product Code: NFO
Regulation Number: 21 CFR 882.5890
Regulation Class: II

3. Predicate Device Information

Predicate Device 1: K221443
Sponsor: XTREEM PULSE LLC
Trade Name: PureLift Pro Plus)
Classification Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Review Panel: Neurology
Product Code: NFO
Regulation Number: 21 CFR 882.5890
Regulation Class: II

Predicate Device 2: K250227
Sponsor: Shenzhen Qianyu Technology Co., Ltd.
Trade Name: JOVS Electric Stimulation Beauty Device (JE2)
Classification Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Review Panel: Neurology
Product Code: NFO
Regulation Number: 21 CFR 882.5890
Regulation Class: II

4. Device Description

The FACEGYM Pro Device (Model: HD-109) is a hand-held device intended to apply electrical impulses to strategic locations on the face and neck. The device electrodes are designed for optimal contact with the face. The device continually alternates the positive and negative electrodes and allows the user to adjust the settings for personalized comfort level by short pressing the power button. The intensity levels starts at (1) and continues to (10).

The casing of this handheld device is composed of polycarbonate and the electrodes consist of zinc alloy & chrome-plated spheres. The device, powered by a 3.7-volt battery, produces low-level current that is transmitted through the two fixed, smooth spherical electrodes. Long press the power button for 1 second to switch on the device, and the indicators will light up on white simultaneously. Users then follow the instructions for use. The two electrodes gently glide over the skin to deliver low-level electrical impulses to strategic locations on the face.

The device is powered by a Lithium-Ion rechargeable battery, and it has a charging cable, resting stand and instruction manual.

5. Intended Use / Indications for Use

The FACEGYM Pro Device (Model: HD-109) is intended for facial and neck stimulation and is indicated for over-the-counter cosmetic use.

6. Comparison to predicate devices

Compared with the predicate devices, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between the subject device and predicate devices do not raise new questions of safety or effectiveness.

Elements of Comparison	Subject device（K253932）	Predicate device 1 (K221443)	Predicate device 2 (K250227)	Remark
510 (K) Number	K253932	K**221443**	K250227	--
Regulation number	882.5890	882.5890	882.5890	Same
OTC/Rx	OTC	OTC	OTC	Same
Regulation Class	Class II	Class II	Class II	Same
Product Code	NFO	NFO	NFO	Same
Indications for Use / Intended use	The FACEGYM Pro Device (Model: HD-109) is intended for facial and neck stimulation and is indicated for over-the-counter cosmetic use.	Intended for facial stimulation and indicated for over-the-counter cosmetic use.	JOVS Electric Stimulation Beauty Device is indicated for over-the-counter aesthetic use including facial and neck stimulation.	Same

Elements of Comparison	Subject device （K253932）	Predicate device 1 (K221443)	Predicate device 2 (K250227)	Remark
Treatment area	Face and neck	Face	Face and neck	Same
Material/ Biocompatibility	PC+ABS Plastic & Zinc alloy	ABS Plastic & Stainless Steel	PC+ABS+PVC+ Stainless steel	Different, note 1
Spheres	Chrome-plated	Chrome-plated	Not publicly available	Different, note 1
Power Source	Lithium battery: 3.7V, 800mAh, 2.96Wh	DC 3.7V Li battery	Adapter input: 5Vd.c, 1A Battery voltage: DC3.7V, 1000mAh	Different, note 2
Sterility	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Same
Human Factors	Ergonomic handheld design	Hand-held device	Ergonomic handheld design	Same
Regulated current or regulated voltage?	Regulated voltage	Regulated current	Regulated voltage	Same
Charging Method	External wall adaptor	External wall adaptor	External wall adaptor	Same
Number of output modes	2	2	2	Same
Number of output channels	1 output channel	1 output channel	1 output channel	Same
Indicator Display:	Yes	Yes	Yes	Same
Patient override control?	Yes	No	Yes	Same
Automatic Shut off ?	Yes	Yes	Yes	Same
Automatic overload trip ?	No	No	No	Same
Duty cycle	0.691	0.63~ 0.80	Not publicly available	Same
Timer Range	5 minutes	10 minutes only	5 minutes	Same
Type of protection	Type BF	Type BF	Type BF	Same
On/off status	Yes	Yes	Yes	Same

Elements of Comparison	Subject device （K253932）	Predicate device 1 (K221443)	Predicate device 2 (K250227)	Remark
Electrical Safety	Compliant with IEC 60601- 1, IEC 60601-1-2, IEC 60601-2-10, IEC60601-1-11	Compliant with ANSI/AAMI ES60601-1 IEC60601-1-2，IEC 60601-2-10，IEC 60601-1-11	Compliant with IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23 FDA Biocompatibility Guidance, Attachment G	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10 ISO 10993-23	Same
Waveform	Pulses Monophasic, alternating polarity	Pulses Monophasic, alternating polarity	Pulsed biphasic, square wave	Same
Shape	Rectangular Pulses	Rectangular Pulses	Modulated Square Wave	Same
Maximum Output Voltage	19.17Vpp@ 500Ω 33.61Vpp @ 2kΩ 49.40Vpp@ 10kΩ	20Vpp(@500Ω)32Vpp(@2kΩ) 44Vpp(@10kΩ)	(+/-10%) 27V@500Ω 35.5V@2kΩ 36.7V@10kΩ	Similar, Note 3
Maximum Current Density	9.314mA @ 500Ω 4.491mA @ 2kΩ 1.207mA @ 10kΩ	9mA(@500Ω) 4.4mA(@2kΩ) 1.2mA(@10kΩ)	(+/-10%) 54mA@500Ω 17.75mA@2KΩ 3.67mA@10KΩ	Similar, Note 3
Frequency range	1.5kHz	1.37kHz～1.73kHz	2.5kHz±20%	Similar, Note 3
Pulse duration	4μs	4μs	Not publicly available	Same
Maximum Phase Charge	6.203μC@ 500Ω	5.81μC@500Ω	7.19μC@500Ω	Similar, Note 3
Maximum Current Density	8.87mA/cm²@ 500Ω	8.8mA/cm2 @500Ω	12.56mA/cm2@500Ω	Similar, Note 3
Maximum Power Density	41.30mW/cm²@ 500Ω	39600μW/cm2	0.178W/cm2@500Ω	Similar, Note 3
Number of pulses per burst	30 pulses	30 pulses	Not publicly available	Same
Burst duration	230μs ±10%	230μs	110μs±20%	Same
ON time (seconds)	Constant	Constant	Constant	Same

Comparison in Detail(s):

Note 1:

Although the "Material/Biocompatibility" is different from the predicate devices, both have the same contact category and duration, and were determined to be compliant with the ISO 10993 series standards' requirements as appropriate. So, these differences do not raise any safety or effectiveness issues.

Note 2:

Although the "Power source" is different from the primary predicate device, they are both powered by an internal lithium battery. The lithium battery of the subject device complies with the IEC 62133-2 standard, and the device complies with IEC 60601-1 and IEC 60601-1-2 requirements, so this difference do not raise any safety or effectiveness issue.

Note 3:

Although the "Maximum Output Voltage", "Maximum Current Density", "Frequency range" "Pulse duration", "Maximum Phase Charge", "Maximum Current Density" and "Maximum Power Density" of subject device are slightly different from the predicate devices, they all comply with IEC 60601-1, IEC 60601-2-10 safety standards' requirements, So, these differences do not raise any safety or effectiveness issues.

7. Test Summary

7.1 Non-Clinical Tests Performed

1) Electrical safety, and electromagnetic compatibility Test

Non-clinical tests were performed on the subject device to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- IEC 60601-1 Edition 3.2 2020-08 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Edition 2.1 2020-07 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 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 62133-2 Edition 1.1 2021-07 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 60601-2-10 Edition 2.2 2023-01 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.

2) Biocompatibility Test

The biocompatibility of the FACEGYM Pro Device (Model: HD-109) has been evaluated according to the FDA Biocompatibility guidance, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'". Components of the device have been determined to conform to ISO 10993-5, ISO 10993-10 and ISO 10993-23 or found to meet the biocompatibility considerations under Attachment G of the FDA Biocompatibility guidance.

3) Software verification and validation

Software verification and validation testing were conducted and documentation was provided as

recommended by FDA'S Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

4) Performance test

The device was evaluated for stimulation performance (e.g. output voltage and current, power density, waveform output, phase charge, burst performance) to verify the output specifications of the device according to Guidance for Powered Muscle Stimulator 510(k)s.

7.2 Summary of Clinical Performance

Clinical testing was not needed for this 510(k) clearance. The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively when used as intended.

8. Date of the summary prepared: July 23, 2026

9. Final Conclusion

The FACEGYM Pro Device (HD-109) has the same intended use as the predicate devices. The differences in technological characteristics do not raise different questions of safety and effectiveness, and the performance data demonstrate that the FACEGYM Pro Device is substantially equivalent to the cleared predicate devices (K221443 and K250227).