January 28, 2026

Ningbo Zhenhai Yihao Electronic Technology Co., Ltd.
℅ Owen He
Consultant
Microkn Medical Technology Service (Shanghai) Co., Ltd.
Room 901, Huafa Center, 889 Pinglu Road
Jing'an District
Shanghai, Shanghai 200040
China

Re: K251622
Trade/Device Name: Hand Massager (SM004D)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: November 28, 2025
Received: November 28, 2025

Dear Owen He:

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,

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.	K251622

Please provide the device trade name(s).

Hand Massager (SM004D)

Please provide your Indications for Use below.

The Hand Massager is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health.

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

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

510(k) #: K251622

510(k) Summary

Prepared on: 2026-01-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ningbo Zhenhai Yihao Electronic Technology Co., Ltd.
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Correspondent Contact	Mr. Owen He
Correspondent Contact Email	fda@microkn.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Hand Massager (SM004D)
Common Name	Powered inflatable tube massager
Classification Name	Massager, Powered Inflatable Tube
Regulation Number	890.5650
Product Code(s)	IRP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K203552	Rapid Reboot	IRP

Device Description Summary

21 CFR 807.92(a)(4)

This hand massager is intended for use by healthy adults to temporarily relieve minor muscle aches and pains in the hand and wrist and to temporarily increase local circulation. It is particularly suitable for relaxing hand muscles after repetitive activities.
Charge this product using the supplied USB cable and a 5 V USB power adapter (1 A or 2 A). Do not use rapid/fast charging or a power adapter that outputs more than 6 V. The power indicator flashes during charging and turns off when fully charged. This product cannot be turned on or operated while it is being charged.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Hand Massager is indicated for temporary relief of minor muscle aches and pains and for a temporary increase in circulation to the treated areas in generally healthy adults.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The device has same indications for use in comparison to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The Proposed Device (Hand Massager, Model SM004D) and the legally marketed Predicate Device (Rapid Reboot) are both Class II powered inflatable tube massager devices, sharing Product Codes IRP and falling under regulatory classification 21 CFR 890.5650. Both devices are indicated for temporary relief of minor muscle aches and pains and for a temporary increase in circulation to the treated areas in generally healthy adults.

Key differences include the power source of the proposed device operates at 5W / DC 5V, whereas the predicate device utilizes a 12VDC power supply with a rechargeable battery system. Both designs comply with the safety requirements of IEC 60601-1. The maximum single-use treatment duration for the proposed device is 20 minutes, which is shorter than the predicate device's maximum single-use duration of 179 minutes. The proposed device's cycle is user-adjustable (10, 15, or 20 minutes), and treatment can be repeated if desired. The shorter maximum duration is considered to present a comparable or reduced risk profile. The proposed device is lighter (0.97 kg) and features a smaller garment sleeve length (29 cm) compared to the predicate device models (weight: 1.81–2.18 kg; sleeve length: 61–84 cm). The device compliant with IEC 60601-1 and do not affect the core therapeutic function or safety. The proposed device utilizes rayon fabric for the garment, which differs from the specific polyurethane laminate construction of the predicate device. The rayon material is characterized as softer, less likely to cause abrasions on human skin and designed for user comfort. All materials used have successfully passed required biocompatibility testing (ISO 10993-5/-10/-23). The user interface and nomenclature for treatment modes differ between the devices. The proposed device offers intensity levels (L1-L6) and a distinct massage sequence mode (P mode), while the predicate device offers two sequential inflation patterns (Mode A and Mode B). Critically, the operational pressure range (0-26.6 kPa) and the fundamental principle of sequential pneumatic compression remain the same. The difference of treatment mode would not raise adversely impact on safety and effectiveness.

Non-clinical testing confirms biocompatibility compliance with ISO 10993-5/-10/-23, electrical safety/EMC conformity to IEC 60601-1/-1-2, electromagnetic immunity in accordance with IEC TR 60601-4-2 and safety requirements for medical electrical equipment used in home healthcare environment per IEC 60601-1-11.

In conclusion, the Proposed Device demonstrates substantial equivalence to the Predicate Device in technical principles, clinical functionality, and safety thresholds. All differences represent design optimizations or validation constraints without introducing new risks, satisfying FDA 510(k) substantial equivalence criteria for market authorization.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical Testing
Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:
IEC60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
IEC TR 60601-4-2:2016, Medical electrical equipment- Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
IEC 60601-1-11:2015, 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.

Biocompatibility test
For the components in contact with the human body, in vitro cytotoxicity test, skin irritation test, and skin sensitization test were conducted according to:
ISO 10993-5:2009, Biological evaluation of medical devices- Part 5: Test 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

Clinical Test Conclusion

No clinical study is included in this submission