May 11, 2026

Jiangsu Jumao X-Care Medical Equipment Co., Ltd.
Yao Yu
General Manager
No.36 Danyan Road
Danyang, Jiangsu 212300
China

Re: K250964
Trade/Device Name: Protable Phlegm Suction Unit (JMA D01)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: JCX
Dated: March 30, 2026
Received: March 30, 2026

Dear Yao Yu:

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.05.11 15:45:12 -04'00'

Colin K. Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250964

Device Name
Protable Phlegm Suction Unit (JMA D01)

Indications for Use *(Describe)*
The device is to be used to remove fluids from the airway or respiratory system. The device creates a negative pressure (vacuum) that draws fluids through disposable tubing that is connected to a collection canister. The fluids are trapped in the collection canister for proper disposal. It is for use on the order of a physician only.

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.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. Submitter's Identifications

Submitter's Name: Jiangsu Jumao X-Care Medical Equipment Co., Ltd.
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2. Correspondent Identifications

Correspondent: Guangzhou Junyi Information Technology Co., Ltd.
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E-mail: jiang13620586569@126.com

3. Name of the Device

Device Classification Name: Apparatus, Suction, Ward use, Portable, Ac-Powered
Regulation Description: Powered Suction Pump
Trade Name: Protable Phlegm Suction Unit
Model: JMA D01.
Classification Panel: General & Plastic Surgery
Product Code: JCX
Regulation Number: 21 CFR 878.4780
Device Classification: Class II

4. The Predicate Devices

Primary Predicate device: K182950 Acara Suction Unit

5. Device Description

The Protable Phlegm Suction Unit, model JMA D01 is to be used to remove fluids from the airway or respiratory system.

The device creates a negative pressure (vacuum) that draws fluids through disposable tubing that is connected to a collection canister.

The fluids are trapped in the collection canister for proper disposal. The device is a rugged, compact and portable electrically operated medical suction device, designed for multi-source powering from AC (External 120 V) mains supply and is ideally suited for field, transport and hospital/clinical use applications.

The Acare canister is an accessory to the Acare Pump and the removed body fluids are collected in it.

The Acare Pump is an AC powered oil-less positive displacement pump capable of delivering up to 600 mmHg of vacuum to draw fluid and small particles.

The Acare Pump has a plastic casing fitted with a power (ON/OFF) button, power indicator, one suction adjustment knob, a suction gauge and a canister holder.

The Acare canister is a preassembled 800 mL canister including canister tubing fitted with a microbial filter at the distal end.

The canister is fitted with a removable lid for fluid containment and an overflow protection device.

The Acare canister should be placed in the in-built canister holder and connect the Acare canister with the Acare Pump via the connectors of the canister tubing prior to use.

6. Indications for Use

The device is to be used to remove fluids from the airway or respiratory system. The device creates a negative pressure (vacuum) that draws fluids through disposable tubing that is connected to a collection canister. The fluids are trapped in the collection canister for proper disposal. It is for use on the order of a physician only.

7. Technology Comparison and Substantial Equivalence Discussion:

	Proposed device	Primary predicate device	Comparison
510k Number	K259064	K182950	
Product Code	JCX	JCX	Same
Proprietary Name	Protable Phlegm Suction Unit	Acare Suction Unit	
Model	JMA D01	ASU-200	
Manufacturer	Jiangsu Jumao X-Care Medical Equipment Co., Ltd.	ACARE TECHNOLOGY CO., LTD.	
Regulation No.	21 CFR 878.4780	21 CFR 878.4780	Same
Classification Name	Apparatus, Suction, Ward Use, Portable, AC-Powered	Apparatus, Suction, Ward Use, Portable, AC-Powered	Same
Class	Class II	Class II	Same

Indications for use	The device is to be used to remove fluids from the airway or respiratory system. The device creates a negative pressure (vacuum) that draws fluids through disposable tubing that is connected to a collection canister. The fluids are trapped in the collection canister for proper disposal. It is for use on the order of a physician only.	The device is to be used to remove fluids from the airway or respiratory system. The device creates a negative pressure (vacuum) that draws fluids through disposable tubing that is connected to a collection canister. The fluids are trapped in the collection canister for proper disposal. It is for use on the order of a physician only.	Same
Product Type	AC-Powered suction pump	AC-Powered suction pump	Same
Electrical requirement	AC 120V, 60Hz	AC 100-240V, 50/60Hz DC 18V	Similar
Power Consumption	135 VA	35 VA	Different
Indication of Vacuum Level	Analogue Vacuum Gauge/760mmHg/100kPa	Analogue Vacuum Gauge/760mmHg/100kPa	Same
Maximum Vacuum (Pressure)	<600mmHg	600 mmHg	Similar
Maximum Flow Rate	24 LPM	24 LPM	Same
Sound Level (Noise level)	Pass ISO 10079-1	Pass ISO 10079-1	Same
Type of Pump	Oil-less Piston pump	Oil-less Piston pump	Same
Pressure Control	adjusted by tuning the knob of vacuum adjusting set	adjusted by tuning the knob of vacuum adjusting set	Same
Disposable Canister	Yes	Yes	Same
Connection tube	Yes	Yes	Same
Patient Tube	Yes	Yes	Same
Overflow protection	Yes	Yes	Same
Bacterial filter	Yes	Yes	Same
Operating Environment	Temp:40°F～100°F (5℃-40℃) Humidity: ≤ 80%RH	Temp: 50˚F~104˚F (10˚C ~40˚C) Humidity:10%-90% RH	Similar
Operating Atmospheric	86KPa~106KPa	700~1060hPa	Similar
Storage Environment	Temp: -20°F～128°F(-29℃-55℃) Humidity:10-90%RH	Temp: 59˚F~122˚F (15˚C ~50˚C), Humidity: 10%～ 90%	Similar

		RH	
Dimensions	(L)355x(W)182x(H)250mm	19.0cm x 11.0cmx 17.5cm	Different
Weight	3.7 kg (2.52 lb)	1.7 kg	Different
Electromagnetic compatibility (EMC) IEC 60601-1-2	Passed	Passed	Same
Basic safety and Essential performance IEC 60601-1 (ANSI/AAMI ES 60601-1)	Passed	Passed	Same
Electrically powered suction equipment - Safety requirements ISO 10079-1	Passed	Passed	Same
Degrees of Protection provided by enclosures (IP Code) IEC 60529	IP 22	IP 21	Different
Substantially Equivalent (SE) Discussions	The proposed device Protable Phlegm Suction Unit products has the same purpose as the predicate device: product code, Regulation No., Classification Name , indications for use, Product Type, Electrical requirement, Indication of Vacuum Level, Maximum Vacuum(Pressure), Maximum Flow Rate , Sound Level(Noise level), Type of Pump, Pressure Control, Disposable Canister, Connection tube, Patient Tube, Overflow protection, Bacterial filter, Operating Environment , Operating Atmospheric, Storage Environment, Compliance with EMC standard IEC 60601-1-2 / Electrical Safety standard IEC 60601-1 and ISO10079-1 for Electrically powered suction equipment -Safety requirements. The difference only exists in such contents: Power Consumption, Dimensions, Weight and Degrees of Protection provided by enclosures (IP Code) IEC 60529. The differences between the proposed and predicate devices do not cause new safety and effectiveness problems. According to the non-clinical test results, the proposed device is as safe, effective and has good performance as the predicate device. The proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.		

8. Non-Clinical Tests

The Protable Phlegm Suction Unit, model JMA D01 has the same intended use and indication for use as the predicate devices. The subject device was compared to the predicate device by testing the electrical specifications, vacuum range, flow rate, power options and operation environment. The results of the Protable Phlegm Suction Unit, model JMA D01 validation studies demonstrate that the Suction Unit perform as intended. The results are summarized as follows:

- The electromagnetic compatibility (EMC) testing performed as described in IEC 60601-1-2 Edition 4.0 2014-02, "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests". The testing results support the device EMC with the intended use environment.
- The protection against electrical hazards from equipment, Protection against excessive temperature and other hazards, hazards situations and fault conditions, construction of equipment and electromagnetic compatibility of equipment and systems, etc. testing performed as described in ANSI/AAMI ES 60601-1:2005+AMD1:2012 + AMD2:2020, "Medical electrical equipment – Part 1: General requirements for basic safety and essential performance". The testing results demonstrated the Protable Phlegm Suction Unit, model JMA D01 met safety and essential performance testing acceptance criteria for each test mentioned above.
- The Measurement of the patient leakage current, Measurement of the vibration and noise of equipment other than the low vacuum equipment, Liquid overflow/ spillage test, Air Leakage test, Interruption of the power supply, Abnormal operation and fault conditions, Environmental tests for equipment for field and/or transport use, Degree of collapse test, Airflow and Vacuum tests, and Resistance to implosion, etc. testing performed as described in ISO 10079-1:2015, "Medical suction equipment Part 1: Electrically powered suction equipment — Safety requirements". The testing results demonstrated the Protable Phlegm Suction Unit, model JMA D01 met Safety requirements testing acceptance criteria for each test mentioned above.
- The classification of degrees of protection provided by enclosures for electrical equipment testing performed as described in IEC60601-1 and IEC 60529-2013, "Degrees of protection provided by enclosures (IP Code)". The testing results demonstrate of the Protable Phlegm Suction Unit, model JMA D01 met IP 22 testing acceptance criteria for each test mentioned above.

8. Conclusions drawn from clinical and non-clinical tests submitted:

The nonclinical tests demonstrate that the proposed device is as safe and effective as the predicate device K182950.