May 14, 2026

Shenzhen HugeMed Medical Technical Development Co., Ltd.
Joyce Huang
Regulatory engineer
Contact Address

Re: K260892
Trade/Device Name: Suction Pump (SU-90)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: [NOTE: Use date of most recent supplement]
Received: March 19, 2026

Dear Joyce 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 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: 2026.05.14 09:51:52 -04'00'

Colin Kejing 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

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.	

Please provide the device trade name(s).

Suction Pump (SU-90)

Please provide your Indications for Use below.

The SU-90 Suction Pump is indicated for vacuum extraction, aspiration during flexible endoscopy and aspiration and removal of surgical fluids, tissue(including bone), gases, bodily fluids or infectious materials from wounds or from a patient's airway or respiratory support system. Intended use in hospital environments.

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

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

I. Submitter

Shenzhen HugeMed Medical Technical Development Co., Ltd.

401, 501, Building 4, Haizhi Technology Park, Fortis, No. 17, Bulan Road, Xialilang Community, Nanwan Street, Longgang District, Shenzhen, Guangdong, 518112, China

Tel.: +86-15992143701

E-mail: huanghuoying@hugemed.cn

Contact Person: Joyce.Huang

Date Prepared: May 11, 2026

II. Subject Device

Name of Device: Suction Pump

Common or Usual Name: Powered suction pump

Classification Name: Pump, Portable, Aspiration (Manual Or Powered)

Regulatory Class: II

Regulation number: 21 CFR 878.4780

Product Code: BTA

Review Panel: General & Plastic Surgery

III. Predicate device

Predicate Device: Basic Suction Pump

510(k) Number: K130123

Product Code: BTA

Manufacturer：Medela AG

IV. Device description

The Suction Pump (Model:SU-90) is equipped with a rechargeable battery and designed to be used in hospital environments. The Suction Pump produces a flow rate not

exceeding 24 L/min and has a maximum vacuum pressure of -90kPa, which is marked “high vacuum - high flow”.

The Suction Pump is mainly composed of diaphragm pump, rechargeable lithium battery, PCB board, display screen, and enclosure.

The Suction Pump is to be used in conjunction with accessories like suction tube, air filters, relief valve and liquid storage bottle (these accessories are outside the scope of this submission). The Suction Pump is a non-sterile device and can be used on multiple patients when following the proper cleaning techniques detailed in the Instructions For Use, but the accessories are all single patient use and should be disposed of properly and in accordance with their respective instructions for use.

V. Indications for use

The SU-90 Suction Pump is indicated for vacuum extraction, aspiration during flexible endoscopy and aspiration and removal of surgical fluids, tissue(including bone), gases, bodily fluids or infectious materials from wounds or from a patient's airway or respiratory support system. Intended use in hospital environments.

VI. Comparison of technological characteristics

The subject and predicate devices differ in flow rate, power source, electrical requirements, and recommended accessories. These differences do not raise new issues on safety or effectiveness of the subject device.

Device Characteristic	Subject Device	Predicate Device
Product Name	Suction Pump	Basic Suction Pump
510(k) Number	K260892	K130123
Product Owner	Shenzhen HugeMed Medical Technical Development Co., Ltd.	Medela AG
Device Classification	878.4780 Powered Suction Pump Class II	878.4780 Powered Suction Pump Class II
Product Code	BTA	BTA
Intended Use	The SU-90 Suction Pump is indicated for vacuum extraction, aspiration during flexible endoscopy and aspiration and	The Basic Suction Pump is indicated for vacuum extraction, aspiration during flexible endoscopy

	removal of surgical fluids, tissue(including bone), gases, bodily fluids or infectious materials from wounds or from a patient's airway or respiratory support system. Intended use in hospital environments.	and aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials from wounds or from a patient's airway or respiratory support system either during surgery or at the bedside.
Prescription vs. OTC	Prescription	Prescription
Maximum vacuum	-90 kPa	-90 kPa
Flow	≤24 l/min	30 l/min
Equipment Type	high vacuum and high flow	high vacuum and high flow
Working Mode	Constant	Constant
Environment of use	In hospital environments	In hospital, ambulatory surgery center, clinic, and doctors' practice.
Power	AC/DC	AC
Voltage	Power adapter input: 100–240 V~, 50/60 Hz; Internal power supply: DC 14.4 V;	100-240 V, 50/60 Hz
Electrical Requirements	Class II, Type BF	Class I, Type CF
IP-Protection	IP22	IP22
Device Dimensions	240*264*128 mm	Rack version: 305*210*375 mm Portable version: 305*285*375 mm Rack/trolley: 510*985*470 mm

Accessories	Air filter； Relief valve and liquid storage bottle; Suction tube; adapter; these accessories are outside the scope of this submission.	Patient tubing; Connectors; Liners; Reusable lids; Jars; Locking clasp; Reusable sets; Vacuum tubing ; Filters; Holders; Accessories for high volume setups; Specimen cups; Wall holders; Vacuum Assisted Delivery cups;
Sterile vs. Non-Sterile	Pump is non-sterile. Disposable components are sterile.	Pump is non-sterile. Disposable components are sterile.
Disposable vs. Non-Disposable	Pump is reusable. Disposable components are single patient use.	Pump is reusable. Disposable components are single patient use.
Operating Environment	Temperature: +5～40 ℃ Humidity: 30 ～ 80 % , non-condensing Atmospheric Pressure: 70 ～ 106 kPa	Temperature: +5～40 ℃ Humidity: 30～75% Atmospheric Pressure: 70～106 kPa
Storage Environment	Temperature: -20～60 ℃ Humidity: 10 ～ 95 % , non-condensing Atmospheric Pressure: 50 ～ 106 kPa	Temperature: -20～55 ℃ Humidity: 20～95% Atmospheric Pressure: 50～106 kPa

Consensus Standards	IEC 60601-1 IEC 60601-1-2 ISO 10079-1	IEC 60601-1 IEC 60601-1-2 ISO 10079-1

VII. Performance data

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

● Bench testing

ISO 10079-1:2022 and ISO 10079-4:2021 were utilized for testing the Suction Pump, with the following parameters tested per the standard:

- Free air flow
- Vacuum level
- Accuracy of vacuum levels
- Protection against ingress of solid objects and liquids
- Noise level

Additionally, the battery use life of the Suction Pump was also tested.

● Electromagnetic Compatibility and Electrical Safety

The Electromagnetic Compatibility and Electrical Safety testing for the Suction Pump was conducted in accordance with:

- IEC 60601-1:2005+A1:2012+A2:2020
- IEC 60601-1-2:2020
- IEC 60601-2-18:2009
- IEC TS 60601-4-2:2024

● Software

The Suction Pump contains software. Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions".

- **Shelf-Life and Service Life**

The shelf life is determined based on product performance testing after accelerated aging test according to ASTM F1980-21.

The service life was validated via accelerated testing according to IEC 62506:2023 and mechanical life testing of key components.

- **Packaging**

Packaging performance was tested in accordance with ASTM D4169 DC13-2023.

VIII. Conclusions

The subject device has the same indication for use and has similar design features and technological characteristics as the predicate device. Performance testing data demonstrates that the subject device is as safe and effective as the predicate device. Accordingly, the subject device is substantially equivalent to the predicate device.