March 7, 2025

ATMOS MedizinTechnik GmbH & Co. KG
Abdulaziz Abdunasimov
Regulatory Affairs Manager
Ludwig-Kegel-Str. 16
Lenzkirch, BW 79853
Germany

RE: K241799
Trade/Device Name: ATMOS C 051 Thorax (317.0200.0); Secretion canister 800 ml (317.1300.0); Hose system (312.1177.0); Hose system with connector small (312.1206.0); Hose system with connector medium (312.1207.0); Hose system with connector large (312.1208.0); Hose system with Y-connector medium (312.1209.0); Hose system with Y-connector large (312.1210.0); Universal bracket for ATMOS C 051 Thorax (316.0200.0); Bracket for ATMOS C 051 Thorax - Standard rail (317.1160.0); Charger Storage for bracket ATMOS C 051 Thorax (317.1170.0); Disposable strap for ATMOS C 051 Thorax (316.1200.0); Hose clamp (061.0079.0)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: February 7, 2025
Received: February 10, 2025

Dear Abdulaziz Abdunasimov:

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,

James H. Jang -S

Digitally signed by James H. Jang -S
Date: 2025.03.07 07:04:37 -05'00'

For

Long Chen, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241799

Device Name
ATMOS C 051 Thorax

Indications for Use *(Describe)*
The ATMOS C 051 Thorax is indicated for aspiration and removal of surgical fluids, tissue, gases, bodily fluids, or infectious material from a patient's respiratory system after surgery. The general indication of the ATMOS C 051 Thorax is thoracic drainage.

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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510(k) Summary – K241799

I. General Information

- Applicant Name: ATMOS MedizinTechnik GmbH & Co. KG
- Applicant Address: Ludwig-Kegel-Str. 16 Lenzkirch BW 79853 Germany
- Applicant Contact Telephone: +49 7653 689236
- Applicant Contact: Mr. Abdulaziz Abdunasimov
- Applicant Contact Email: regulatory@atmosmed.de
- Date Prepared: March 5, 2025

II. Device Name

- Device Trade Name: ATMOS C 051 Thorax

- Accessories Trade Name: Secretion canister 800ml;
  Hose system;
  Hose system with connector small;
  Hose system with connector medium;
  Hose system with connector large;
  Hose system with Y-connector medium;
  Hose system with Y-connector large;
  Universal bracket for ATMOS C 051 Thorax;
  Bracket for ATMOS C 051 Thorax - Standard rail;
  Charger Storage for bracket ATMOS C 051 Thorax;
  Disposable strap for ATMOS C 051 Thorax;
  Hose clamp

- Common Name: Powered suction pump
- Classification Name: Pump, Portable, Aspiration (Manual Or Powered)
- Regulation Number: 878.4780
- Product Code(s): BTA
- Class: Class II
- Review Panel: General and Plastic Surgery

III. Legally Marketed Predicate Device(s)

- 510(k) Number: K103042
- Trade Name: ATMOS E 201 Thorax and ATMOS S 201 Thorax
- Product Code: BTA

IV. Device Description

The ATMOS C 051 Thorax (317.0200.0) drainage system is a device for mobile, digital thoracic drainage. It is portable, mains-independent and has an electronic monitoring system with optical and acoustic display. The device takes medical effect as a system in combination with a secretion canister and a hose system. The system creates the (natural) vacuum in the pleural cavity by draining off air and secretion.

The ATMOS C 051 Thorax is equipped with a rechargeable battery. A charging unit which is located within the suction device guarantees the secure charging of the battery.

The hose system is rinsed with air at regular intervals to prevent the collection of debris in the hose. Bacterial and viral filters in the secretion canister and measuring hose prevent contaminated secretions from entering the device. The device is equipped with a disposable strap and a carrying handle. These enable mobility. A universal bracket or the standard rail bracket can be ordered separately as accessories.

The ATMOS C 051 Thorax is a reusable device delivered in non-sterile state. The secretion canister and hose systems are single-use devices and delivered sterile. All other accessories subject to this submission are reusable and delivered non-sterile.

V. Indications for Use

The ATMOS C 051 Thorax is indicated for aspiration and removal of surgical fluids, tissue, gases, bodily fluids, or infectious material from a patient's respiratory system after surgery. The general indication of the ATMOS C 051 Thorax is thoracic drainage.

VI. Indications for Use Comparison

The subject ATMOS C 051 Thorax and the predicate ATMOS S 201 Thorax are both devices for mobile, digital thoracic drainage. Both devices have the same indications for use - aspiration and removal of surgical fluids, tissue, gases, bodily fluids, or infectious material from a patient's respiratory system after surgery. The general indication is thoracic drainage.

VII. Technological Comparison

The ATMOS C 051 Thorax has the same technological characteristics regarding operation principle, use and type of accessories, vacuum control and maximum vacuum compared to the predicate device ATMOS S 201 Thorax.

The following differences exist:

- Size and weight: The subject secretion canister has only 800 ml compared to 2 L of the predicate canister, and the subject device weighs only 1.16 kg compared to 3.27 kg of the predicate device.
- Home use: Home care use is possible with the subject device but not for the predicate device.
- Pump performance: Free flow rate is lower for the subject device (5 +/- 0.5 L/min) compared to the predicate device (18 +/- 2 L/min).

The completed verification and validation tests, as well as human factors validation and risk management activities, show that these differences do not raise new or different questions of safety and/or effectiveness.

VIII. Summary of Non-Clinical and/or Clinical Tests

Performance tests were carried out to ensure that the subject device functions as intended and meet design specifications. The following performance data were provided in support of substantial equivalence determination:

- Electrical, Mechanical, and Thermal Safety

  The ATMOS C 051 Thorax has been successfully tested for electrical, mechanical, and thermal safety in accordance with AAMI/ANSI and IEC 60601 standards and complies with IEC 60601-1, IEC 60601-1-2, and IEC 60601-4-2.

- Software

  The ATMOS C 051 Thorax contains software. The documentation level for the device software is considered to be "enhanced." Software validation activities were performed in accordance with the FDA guidance "Content of Premarket Submissions for Device Software Functions," issued on June 14, 2023. To fulfill the requirements with regard to cybersecurity, the FDA guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions," issued on September 27, 2023, was followed.

- Biocompatibility Testing

A biological evaluation was performed according to ISO 10993-1 and followed the recommendations in the FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," issued September 8, 2023, including Attachment G: Biocompatibility of Certain Devices in Contact with Intact Skin.

- Performance Bench Testing

The completed tests include tests with regard to design and performance, as well as human factors validation. Risk analysis was carried out based on acceptance criteria established in accordance with ISO 14971.

The following bench performance tests of ATMOS C 051 Thorax were performed with no unexpected results or significant deviations:

- Maximum flow rate
- Function and accuracy of flow display
- Minimum to maximum vacuum
- Function, accuracy and control delay of vacuum display
- Battery operation at full power mode
- Battery charge time
- Over suction protection
- Weight
- Alarm sound and noise level
- Length of hose system

Human factors validation:

A usability engineering process has been performed in accordance with IEC 62366-1:2015+Cor1:2016+A1:2020, IEC 60601-1-6:2010+A1:2013+A2:2020, and FDA guidance document “Applying Human Factors and Usability Engineering to Medical Devices,” issued on February 3, 2016. FDA draft guidance “Content of Human Factors Information in Medical Device Marketing Submission,” issued on December 9, 2022, has been followed as well. The use-related risk analysis lists all identified risks associated with the use of the device. The human factors (HF) engineering report summarizes the conducted HF testing. The performed human factors validation shows that the use of the device is safe, especially with regard to the use by lay persons. The residual risks that

remain after HF validation testing for the ATMOS Thorax C 051 have been reviewed and determined to be acceptable.

A risk management process is routinely performed by ATMOS as part of the product development in accordance with ISO 14971:2019. The Risk Management Documentation specifies all identified risks and summarizes all conducted risk management activities. Risks specifically related to the home use of the subject device have been considered in the risk management. The benefit-risk analysis shows that the overall benefits of using the device outweigh the risks. The device is safe and effective for use in the intended patient population.

- Reprocessing, Sterility, and Shelf-Life

  Required cleaning and disinfecting procedures for the ATMOS C 051 Thorax are described in the instructions for use. A sterile validation was performed for the secretion canister and hose systems. Sterilization was performed according to ISO 11135.

IX. Conclusion

The performance testing demonstrates that the ATMOS C 051 Thorax is as safe and effective as, and substantially equivalent to, the predicate device for the same intended use. Any differences between the subject and predicate devices do not raise new or different questions of safety and effectiveness.