April 26, 2025

Cro, LLC
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K251101
Trade/Device Name: AIRO Suction Unit (AIRO-01)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: BTA
Dated: April 11, 2025
Received: April 11, 2025

Dear Dave Yungvirt:

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: 2025.04.26 11:24:41 -04'00'

James Jang, 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)*
K251101

Device Name
AIRO Suction Unit (AIRO-01)

Indications for Use *(Describe)*
The AIRO Suction Unit, Model AIRO-01, is a portable, battery-powered medical suction device intended for use in emergency airway management procedures by professional medical providers. It is intended for intermittent operation to remove secretions, such as blood or vomit, during airway management procedures and other procedures for which an intermittent suction medical device may be applicable. The device is indicated for the suctioning of adult patients.

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.

510(k) Summary

510(k) #: K251101

Prepared on: 2025-04-23

Contact Details 21 CFR 807.92(a)(1)

Applicant Name	CRO, LLC
Applicant Address	516 E Spruce St. Missoula MT 59802 United States
Applicant Contact Telephone	14065404089
Applicant Contact	Mr. Jeffrey Boardman
Applicant Contact Email	jboardman@cromedical.com

Device Name 21 CFR 807.92(a)(2)

Device Trade Name	AIRO Suction Unit (AIRO-01)
Common Name	Powered suction pump
Classification Name	Pump, Portable, Aspiration (Manual Or Powered)
Regulation Number	878.4780
Product Code(s)	BTA

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name	Product Code
K041154	S-SCORT...JR QUICKDRAW, MODEL 2400	BTA

Reference #	Reference Trade Name	Product Code
K153459	TACVAC	BTA

Device Description Summary 21 CFR 807.92(a)(4)

The AIRO Suction Unit, Model AIRO-01, is a compact, handheld, portable battery-powered medical suction device intended for use in emergency airway management procedures by professional medical providers such as emergency medical technicians, paramedics, and hospital personnel. The device is not intended for contact with patient tissue during procedures. It is intended for intermittent operation to remove secretions, such as blood or vomit, during airway management procedures and other procedures for which an intermittent suction medical device may be applicable. The device is indicated for the suctioning of adult patients.

Principles of Operation:

The AIRO Suction Unit operates by generating negative pressure to aspirate fluids through a disposable suction tubing and a single-use collection bag made of flexible, durable plastic

rather than a rigid plastic canister. It functions as an intermittent suction device, meaning the user activates suction as needed rather than providing constant suction.

Key Principles of Operation:

- A 12V DC motor-driven pump generates negative pressure.
- Fluids are directed into a 500mL disposable collection bag to prevent contamination and overflow.
- The user selects suction levels appropriate for the procedure.
- The device is powered by a lithium battery pack (four 3.7 V / 680 mAh CR123 rechargeable batteries), allowing full portability in emergency scenarios. Batteries are included but not installed and are recharged through an external charger that is not included in this submission.
- The disposable collection bag (AIRO-DSP) has dimensions of L 6.00" x W 4.119" x D 2.255" and is made of a 4 mm thick plastic polybag attached to a Nylon-40 disposable body (depth of 2.255" including disposable body), which attached into the main body of the AIRO Suction Unit.
- The AIRO Suction Unit is compatible with standard third party disposable airway suction tubing and catheters, including:
- Standard Disposable Suction Tubing (9/32" ID x 36" L)
- Standard Disposable Suction Catheters (e.g. Yankauer, DuCanto, others)
- Tubing and catheters are third party items purchased by the end user and are not included in this submission.

Modes of Operation:

The AIRO Suction Unit is capable of achieving a continuous range of vacuum pressures from 20 mmHg to 550 mmHg, allowing the user to adjust suction based on clinical need. The device has been validated to meet ISO 10079-1:2015 standards, which define three vacuum levels for testing:

- Low Vacuum: ≤ 150 mmHg (≤ 20 kPa).
- Medium Vacuum: 150 - 450 mmHg (20 - 60 kPa).
- High Vacuum: ≥ 450 mmHg (≥ 60 kPa).

The AIRO Suction Unit provides precise control across this vacuum range, ensuring safe and effective operation in emergency and clinical settings. ISO 10079-1:2015 defines Low Flowrate devices as a free air flowrate of less than 20 LPM; AIRO achieves all of these vacuum levels while maintaining a low flowrate of less than 20 LPM.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The AIRO Suction Unit, Model AIRO-01, is a portable, battery-powered medical suction device intended for use in emergency airway management procedures by professional medical providers. It is intended for intermittent operation to remove secretions, such as blood or vomit, during airway management procedures and other procedures for which an intermittent suction medical device may be applicable. The device is indicated for the suctioning of adult patients.

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

The subject device and predicate / reference device have the same indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

There are technological differences between the subject and the predicate devices. Overall, these differences increase the portability and usability of the device in the intended use settings but do not raise new questions of safety and effectiveness as the differences have been evaluated through safety and performance testing (ES/EMC, biocompatibility, Use-Life, reprocessing, software V&V, etc.). Therefore, AIRO can be considered substantially equivalent to the SSCOR Quickdraw and the Athena GTX TACVAC.

Device & Predicate Device(s):	Subject Device AIRO Suction Unit (model AIRO-01	Predicate Device S-SCORT Jr Quickdraw Model 2400 K0153459	Reference Device TACVAC K153459	Significant Difference
General Device Characteristics				
Dimensions	L 7.58” x W 3.25” x H 2.5”	L 10.5” x W 4.35” x H 4.5”	L 7.25”x W 11.88” x H 3.0”	Similar
Weight	1.3 lbs. without batteries	2.6 lbs.	0.575 lbs.	Similar
Vacuum pressure	20-550 mmHg	80-500 mmHg	300 mmHg	Similar / Different
Nominal airflow rate	0.75 LPM	>30 LPM	5 LPM	Different
Motor type	12 VDC	12 VDC	6 VDC	Same / Different
Power source	4x CR123 3.7 V / 680 mAh Li-ion battery	10x AAA Alkaline Battery (15 V)	2x CR123A (6 V)	Similar / Different
Tip dimension	9/32” ID x 36” L (7.1 mm ID x 91.44 cm)	9/32” ID x 36” L (7.1 mm ID x 91.44 cm)	9/32” ID x 36” L (7.1 mm ID x 91.44 cm)	Same
Canister capacity	500 mL	300 mL	500 mL	Different / Same
Water protection	IP33	IPX4	IPX4	Same

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

AIRO Suction Unit was tested to ISO 10079-1 [1-157] and ISO 10079-4 demonstrating safety and performance. All applicable clauses were successfully executed, meeting the established criteria.

A distribution study was performed to a recognized international standard (ISTA) yielding packaging is sufficient to maintain device functionality.

A usability study was performed employing users expected to operate the device. Results indicate the device performs adequately for the target user group.

The subject device is substantially equivalent to the predicate device.