May 7, 2025

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

Re: K251111
Trade/Device Name: Cary
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: JCX
Dated: April 10, 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: 2025.05.07 13:27:17 -04'00'

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)*

K251111

Device Name
Cary

Indications for Use *(Describe)*

Cary is indicated for removal of fluids from the upper airway. The device creates a negative pressure (vacuum) that draws fluids through disposable suction tube that is connected to a disposable collection canister. The fluids are captured in the collection canister for proper disposal. Cary is for use only on the order of a physician or other licensed practitioner (e.g. Emergency Medical Technician in field use).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 K251111 7 May 2025

Submitter

Applicant Name:	Excitus AS
Applicant Address:	Hillevågsveien 101, 4106 Stavanger, Norway
Applicant Phone:	+47 971 57 784
Applicant contact:	Øystein Refseth, CEO, or@excitus.no
Correspondent Name:	Innokas Medical Oy
Correspondent Address:	Metsänneidonkuja 8 Espoo 02130 Finland
Correspondent Phone:	+358 40 5856625
Correspondent Contact:	Minna Eskola, QA/RA Specialist, minna.eskola@innokasmedical.fi

Device Classification

Trade Name:	Cary
Common Name:	Powered suction pump
Classification Name:	Apparatus, Suction, Ward Use, Portable, Ac-Powered
Regulation Number:	878.4780
Product Code:	JCX

Legally Marketed Predicate Device

Predicate:	K120065
Predicate Trade Name:	Laerdal Compact Suction Unit 4 (LCSU 4)
Product Code:	JCX

Device Description Summary

[Cary] is a handheld, electrically powered medical suction device used to clear the upper airway during emergency care. It consists of a reusable drive unit and disposable collection container (pumpister) and tubing. The drive unit powers a piston pump, creating negative pressure (vacuum) in the disposable collection container. The vacuum draws fluids and other matter through a disposable tubing connected to the container, where they are collected for disposal. The size and shape of the device enable use by one hand, and a rechargeable lithium-ion battery allows field and transport use of the device.

Intended Use / Indications for Use

Indications for use: Cary is indicated for removal of fluids from the upper airway. The device creates a negative pressure (vacuum) that draws fluids through disposable suction tube that is connected to a disposable collection canister. The fluids are captured in the collection canister for proper disposal. Cary is for use only on the order of a physician or other licensed practitioner (e.g. Emergency Medical Technician in field use).

Device operation: Cary is a non-sterile, portable, handheld, battery-powered medical suction device designed for field and transport use and for evacuation of fluids.

Intended patient population: adult patients

Intended users: a physician or other licensed practitioner (e.g. Emergency Medical Technician in field use)

Indications for Use Comparison

Subject device Cary is indicated for removal of fluids from the upper airway and the predicate device is to be used to remove fluids from the airway or respiratory support system. This is similar between the subject device and predicate device, with the suction tip length of subject device Cary ensuring use in the upper airway.

Subject device Cary creates a negative pressure (vacuum) that draws fluids through disposable suction tube that is connected to a disposable collection canister. The fluids are captured in the collection canister for proper disposal. This is the same between the subject device and predicate device.

Subject device Cary is for use only on the order of a physician or other licensed practitioner (e.g. EMT-field use). This is the same between the subject device and predicate device.

The indications for use of the subject device and predicate device are essentially the same.

The restriction to use subject device Cary in the upper airway does not affect the safety and effectiveness of the subject device when compared to the predicate device as the design of the subject device (suction tip) ensures use as indicated and efficacy of performance (clearance of airway to allow respiration or ventilation).

Comparison of patient population

Subject device Cary and the predicate device are intended to be used for adult patients. This is the same between the subject device and predicate device.

Technological Comparison

The technological characteristics of the Excitus Cary are functionally equivalent to the predicate device, the Laerdal Compact Suction Unit 4 (LCSU 4).

Device & Predicate Device(s):	Subject Device Cary model IM006764	Predicate Device Laerdal Compact Suction Unit 4 (LCSU 4) K120065	Significant Difference
General Device Characteristics			
Operation	Continuous	30 min ON, 30 min OFF (intermittent)	Different
Air leakage	< 1 kPa	Not specified	--
High vacuum	≤600 mmHg	≤550 mmHG	Similar
Low vacuum	≤100	50 mmHg	Similar
High flow rate	≥ 20 l/min	30 l/m	Similar
Low flow rate	< 20 l/min	Not specified	--
Vacuum indicator accuracy	No indicator	5% of full scale	Different
Noise level	70.5 dB	Not specified	--
Collection capacity	300 ml	300 ml	Same
Suction tubing diameter	8 mm ID	6.6 mm ID	Similar
Power Supply	14.4V, 2900mAh Li-Ion internal Battery. Cary cannot be used during charging cycle	NiMH 12V, 1.6 Ah internal Battery LCSU 4 can be operated during charging cycle	Similar / Different
Battery runtime	3 hours	45 minutes	Different
Ingress protection classification	IP54	IP33	Different

While there are some differences in the materials that comprise the drive unit (main unit), pumpister (container), and suction tip (suction tubing) of the Cary, the strength and durability of the materials, and suitability for the intended use are comparable to those of the predicate device. Material of the subject device in direct contact with the human body was assessed for biocompatibility in accordance with ISO10993-1, 5, 10, 11, 18, 23: Biological Evaluation of Medical Devices.

Suction performance of Cary is similar to LCSU 4 when it comes to free air flow and vacuum levels. Cary can be used in any position while holding in hand whereas LCSU 4 shall be placed upright. Collection capacity in the devices is the same.

The weight of Cary is less than that of LCSU 4 and dimensions of Cary more compact than the size of LCSU 4. User interface for vacuum level adjustment is implemented with a toggle switch in Cary and with a vacuum regulator in the predicate device LCSU 4.

Medical electrical equipment classification of the subject device is comparable to that of the predicate device. Unlike the predicate, subject device can be charged safely from sockets that are and those that are not protective earthed.

Cary uses rechargeable lithium-ion (li-ion) battery as energy source, whereas LCSU 4 includes a nickel–metal hydride (NiMH) battery. Battery runtime of Cary is longer than that of LCSU 4.

Excitus has submitted performance testing for the above referenced design differences with this 510(k) that demonstrate that the Cary is as safe and effective as the predicate device.

Non-Clinical Tests Summary and Conclusions

Recognized Consensus Standards

1-157 ISO 10079-1 Fourth edition 2022-03 Medical suction equipment - Part 1: Electrically powered suction equipment, and ISO 10079-4 First edition 2021-08 Medical suction equipment - Part 4: General requirements, and Guidance for Industry and FDA Reviewers/Staff Guidance Document for Powered Suction Pump 510(k)s have been adopted as special controls applicable to this device.

The following non-clinical testing are provided in support of the substantial equivalence determination.

Operating position

Ability of Cary to operate in any spatial orientation was tested and confirmed.

Protection devices

Overfill protection and protection against reverse flow were tested to ensure the compliance of Cary protection devices. The results of the testing were within the acceptance criteria.

Noise

The maximum A-weighted sound pressure level was tested for Cary. The result was within the acceptance criteria apart from 0,5dB excess when the suction tip was blocked. This is considered as an acceptable deviation from the standard requirement as it does not decrease the safety or effectiveness of the subject device when compared to the predicate device.

Air leakage

Leakage into the collection container assembly was verified for Cary as per standard requirement for general use suction equipment. The results of the testing were within the acceptance criteria.

Vacuum levels and free air flows

Vacuum levels and free air flows for categories High vacuum/high flow and Low vacuum/low flow were tested for Cary. The results of the testing were within the acceptance criteria.

Pharyngeal suction equipment

Ability of Cary to evacuate ≥ 200 ml of simulated vomitus in not more than 10 s was tested. The result of the test was within the acceptance criteria.

Reprocessing Validation

An assessment was conducted for the appropriateness of the manual reprocessing process and for the ability of the intended user to carry out the reprocessing of Cary drive unit per provided instructions (human factors validation testing including reprocessing instructions). The outcome of the validation was within the acceptance criteria.

Sterilization and Shelf-Life

Cary is not provided as sterile. Shelf-life is applicable only to a filter in Cary pumpister. The filter is not sterile but its shelf-life, determined by the supplier, defines the expiration date of the pumpister which is included the pumpister label. Shelf-life testing is not required for usage of the filter in Cary pumpister.

Biocompatibility

Biocompatibility of direct-contact material in Cary was confirmed by assessing the cytotoxicity, sensitization, irritation, acute systemic toxicity, and material mediated pyrogenicity testing in accordance with ISO 10993-1,-5,-10,-11,-18,-23: Biological Evaluation of Medical Devices.

Software

Software verification and validation were conducted, and documentation provided as recommended by FDA's Guidance "Content of Premarket Submissions for Device Software Functions -Guidance for Industry and Food and Drug Administration Staff". Cary software is classified as CLASS B under the Software Safety Classification per IEC 62304:2006+AMD1:2015 Medical device software - Software life cycle processes, and the software documentation level is “Basic Documentation Level” based on the Guidance "Content of Premarket Submissions for Device Software Functions -Guidance for Industry and Food and Drug Administration Staff".

EMC and Electrical Safety

The electromagnetic compatibility (EMC) and electrical safety (ES) of Cary were confirmed by the following standards: IEC 60601-1-2:2014+AMD1:2020; IEC 60601-1:2005+AMD1:2012+AMD2:2020; ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]

Conclusion

The result from the comparison between Cary and the predicate device LCSU 4 and from the test reports is that the subject device Cary performs acceptably and does not raise any different questions regarding safety or effectiveness, thus supporting a determination of substantial equivalence.