



March 4, 2026

LifeVac LLC
% Natalya Valerio
Consultant
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: DEN250012

Trade/Device Name: LifeVac

Regulation Number: 21 CFR 874.5400

Regulation Name: Suction anti-choking device as a second-line treatment

Regulatory Class: Class II

Product Code: QXN

Dated: April 11, 2025

Received: April 11, 2025

Dear Natalya Valerio:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the LifeVac, an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

The LifeVac is a non-powered, non-invasive, single-use-only airway clearance device intended to resolve choking in a victim with a complete airway obstruction when a current choking protocol has been followed without success. LifeVac should only be used to remove an object/food from a victim with a complete airway obstruction. LifeVac is intended for use on adult or pediatric choking victims who are at least 1 year of age. LifeVac can be administered by a lay person or a medical professional (18 years or older) in various settings including at home or nursing homes, restaurants, schools, and other outside environments.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the LifeVac, and substantially equivalent devices of this generic type, into Class II under the generic name suction anti-choking device as a second-line treatment.

FDA identifies this generic type of device as:

Suction anti-choking device as a second-line treatment. A suction anti-choking device as a second-line treatment is intended to be used, by application of suction, to resolve choking in victims experiencing complete airway obstruction. The device is intended to be used as a second-line treatment in an emergency situation after unsuccessful use of a basic life support (BLS) choking protocol.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On April 11, 2025, FDA received your De Novo requesting classification of the LifeVac. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the LifeVac into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the LifeVac can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Injury or death from choking <ul style="list-style-type: none"> • due to delayed initiation of basic life support (BLS) choking protocol • due to use error • due to inadequate suction • due to device failure 	Clinical information Postmarket surveillance Non-clinical performance testing Human factors testing Training Labeling
Injury to oral/oropharyngeal tissue <ul style="list-style-type: none"> • due to device use • due to use error • due to device failure 	Clinical information Postmarket surveillance Non-clinical performance testing Human factors testing Training Labeling
Adverse tissue reaction	Biocompatibility evaluation

In combination with the general controls of the FD&C Act, the suction anti-choking device as a second-line treatment is subject to the following special controls:

- (1) Premarket clinical information, or a combination of premarket clinical information and postmarket surveillance (in accordance with special control (2)), must demonstrate, in the intended patient population:
 - (i) How often the device is used consistent with anticipated conditions of use, including how often the device is used after unsuccessful use of a BLS choking protocol and how often the device is used on patients experiencing a complete airway obstruction;
 - (ii) The delay in initiating a BLS choking protocol due to use of the device;
 - (iii) The rate of successful device use to resolve choking; and
 - (iv) The adverse event profile of the device, including injuries and device malfunctions.
- (2) Information obtained from postmarket surveillance must demonstrate the information described in special control (1)(i)-(iv), in consideration of the premarket information obtained in accordance with special control (1), unless FDA determines, based on the totality of the premarket information, that information from postmarket surveillance is not required for such demonstration. Such postmarket surveillance must be conducted per a protocol determined appropriate by FDA for such demonstration (in consideration of the premarket information obtained in accordance with special control (1)), and must include initiation, enrollment, and reporting requirements to ensure timely periodic updates to FDA on postmarket surveillance progress and outcomes.
- (3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:
 - (i) Verification of device performance in dislodging a complete obstruction in representative simulated airway models;
 - (ii) Verification of pressures generated; and
 - (iii) Verification of device and material durability.
- (4) The patient/user-contacting components of the device must be demonstrated to be biocompatible.
- (5) Human factors testing must demonstrate that the device can be used as intended based on the device user interface and directions for use.
- (6) Training must be included with sufficient educational elements so that upon training completion, the user can correctly use the device, including identification of a complete airway obstruction and performance of a BLS choking protocol.
- (7) Labeling must include the following:
 - (i) Instructions to use the device only in the event of complete airway obstruction and after a BLS choking protocol fails;
 - (ii) Description and access to the training required in special control (6); and
 - (iii) A summary of any completed postmarket surveillance data collected as required by special control (2), including updated labeling to accurately reflect outcomes observed in postmarket surveillance.

In order to satisfy special control (1) and (2) above, and in consideration of the premarket clinical information provided, FDA has determined that you must conduct postmarket surveillance. FDA has determined that to be an appropriate protocol as described in special control (2), your protocol for conducting such postmarket surveillance must collect data with the LifeVac acquired under anticipated conditions of use and in the intended patient population, with a justified sample size. This protocol must include:

Study(ies) of device users' behavior and device use, including survey data and real-world data that is routinely collected, that determines:

- Rate at which device successfully resolves choking
- Adverse events both related to device and to all procedures that were used on a choking patient
- Whether users called 911 and performed a BLS choking protocol
- Whether device was used on patients experiencing a complete airway obstruction
- Whether there is a delay in initiating a BLS choking protocol due to device use

Within 30 days of receipt of this order, you must submit a complete study protocol for your study(ies) as described above. FDA expects to work with you to determine that your study protocol is appropriate as described in special control (2) within 60 days of this order. Your submission should be clearly labeled "Postmarket Study Protocol" and submitted to the Agency as specified below. Please reference the De Novo number above to facilitate processing. If there are multiple protocols being finalized after granting of this De Novo request, please submit each protocol as a separate submission, identified by their unique study name(s).

From the date the study protocol is determined to be appropriate, you must meet the following timelines:

- First subject enrolled within 6 months
- 20% of subjects enrolled within 18 months
- 50% of subjects enrolled within 36 months
- 100% of subjects enrolled within 60 months

In addition, to ensure timely periodic updates to FDA on postmarket surveillance progress and outcomes consistent with special control (2), you must submit separate periodic reports on the progress of the study(ies) as follows:

- Postmarket surveillance progress reports every six (6) months until subject enrollment has been completed, and annually thereafter, from the date the protocol is determined to be appropriate, unless otherwise specified by FDA.
- If any enrollment milestones are not met, you must begin submitting enrollment status reports every three (3) months, in addition to your periodic postmarket study progress reports, until enrollment has been completed, or FDA notifies you otherwise.
- Submit the final postmarket study report three (3) months from study completion (i.e., last subject's last follow-up date).

Each postmarket surveillance report should be submitted to the Agency as specified below, identified "Postmarket Surveillance Report" in accordance with how the study is identified above, and bearing the applicable De Novo reference number.

Be advised that failure to comply with any special control requirement, including the postmarket surveillance initiation, enrollment, completion, and reporting per the postmarket surveillance protocol determined to be appropriate by FDA as outlined above, may result in the adulteration and misbranding of your device.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the suction anti-choking device as a second-line treatment they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 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>.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above De Novo number to facilitate processing.

Postmarket Mandated Studies Program
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Alternatively, documents can be submitted electronically through the CDRH Portal. For more information on the CDRH Portal, please visit <https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal>.

If you have any questions concerning the contents of the letter, please contact Joyce Lin, Ph.D., at 301-796-5544.

Sincerely,

Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health