DE NOVO CLASSIFICATION REQUEST FOR LIFEVAC

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 874.5400

CLASSIFICATION: Class II

PRODUCT CODE: QXN

BACKGROUND

DEVICE NAME: LifeVac

SUBMISSION NUMBER: DEN250012

DATE DE NOVO RECEIVED: April 11, 2025

SPONSOR INFORMATION:

LifeVac LLC
110 Lake Ave South
Suite 35
Nesconset, NY 11767

INDICATIONS FOR USE

The LifeVac is indicated as follows:

> 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.

LIMITATIONS

PRECAUTIONS

- Only use LifeVac on the face
- The LifeVac unit is not guaranteed to resuscitate a victim
- Use at your own risk
- LifeVac is not responsible for injury and/or death as result of use

WARNINGS

- To reduce risk of injury and/or death, **READ** and **FOLLOW** provided instructions
- **LIFEVAC IS NOT A TOY**: Keep out of reach of children
- Use of device may result in bruising of the face from the application of the mask, coughing after removal of the object inside of mouth, and hypersensitivity to plastic

CONTRAINDICATIONS FOR USE

- Patients with an endotracheal tube already in place
- Non-choking individuals (e.g., drowning victim, people with breathing difficulty such as asthma, or individuals breathing on their own)
- Children under 1 year of age

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

LifeVac is a portable, non-powered, single-use, non-sterile device that generates suction to remove a complete foreign body airway obstruction from a choking victim after a standard choking rescue protocol has failed. The device consists of a plunger with a one-way valve. A face mask is attached prior to use. The device is shown in Figure 1.

Figure 1. LifeVac device

The LifeVac device with the attached mask is placed over the victim's nose and mouth creating a mask seal. The device handle is pressed down to compress the unit, which pushes the air out through the vent system on the bottom of the device and not into the patient. The handle is then quickly pulled up and negative pressure is generated to suction out the obstruction. The duration of suction is minimal.

The device has a patented ball valve system which is designed to prevent any air from exiting through the mask. The valve also is designed to prevent air from pushing stuck food or foreign objects downward. This creates a one-way suction to remove the lodged object.

The device is non-invasive and does not need to be placed into the oral cavity.

LifeVac device is available as a Home Kit (Figure 2) or Travel Kit (Figure 3). The device is the same in both kit presentations and the only difference is the Home Kit comes with 1 adult mask, 1 pediatric mask, and 1 practice mask while the Travel Kit does not include a practice mask.

Figure 2. LifeVac Home Kit

Figure 3. LifeVac Travel Kit

SUMMARY OF NONCLINICAL/BENCH STUDIES

Nonclinical studies of the LifeVac device consisted of biocompatibility evaluation, bench studies, cadaveric studies, packaging/shipping, device function testing and human factors assessment, as described below.

BIOCOMPATIBILITY

The biocompatibility evaluation of LifeVac was conducted in accordance with the International Standard ISO 10993-1:2018 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process." LifeVac was classified as a surface device with direct contact with skin, with limited contact duration (<24 hours). Based on the contact type and contact duration, the biocompatibility tests included Cytotoxicity, Sensitization and Irritation. The testing demonstrated that LifeVac met the biocompatibility requirements based on the nature and duration of contact.

PACKAGING TESTING AND DEVICE DURABILITY

Conditioning and package testing was performed on LifeVac devices in the following packaging configurations: palletized unit load of cartons, individual cartons, and envelopes. The packages underwent environmental conditioning following the standard ASTM D4332-22 *Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing*, and simulated transportation following the standard ASTM D4169-22 *Standard Practice for Performance Testing of Shipping Containers and Systems*. Following these methods, the packages and devices were visually inspected to ensure they maintained their mechanical integrity, and a subset of devices was tested to evaluate their functional performance. All packaging configurations passed visual inspection (of both the package and device) and functional testing. The devices maintained their mechanical and functional integrity, as they were free of deformation and free of cracks and could generate negative pressure.

The device labeling includes instructions for proper storage of the device and visual inspection of both the masks and the suction unit for defects, cracks, discoloration or expiration, to encourage maintenance of device mechanical and functional integrity throughout storage and for its indicated use.

PERFORMANCE TESTING – BENCH

Characterization of Generated Pressures

The bench testing characterized the "inbound" pressure (pressure decrease [i.e. vacuum pressure]) resulting from the extension of the device) and the "outbound" pressure (pressure increase from compressing the device) under different conditions of LifeVac use. Both pressures were measured under 4 use scenarios: 1) intended use: with and without obstruction (with multiple validated boluses placed at the level of the larynx), 2) unintended use: when a mismatched mask was used (e.g., an adult mask on a pediatric airway or a pediatric mask on an adult airway), 3) unintended use: when an expired mask was used, and 4) unintended use: when a mask seal was compromised. This testing used two custom model systems: 1) representative airway volume (benchtop test fixtures) representing the smallest and largest volumes, and 2) airway manikins of the infant, child and adult sizes, utilizing a closed system and incorporating pressure measurements at various locations (at the oral cavity and above the bolus).

The results showed that regardless of the airway size and use scenarios, the device was able to generate inbound pressure sufficient to move the bolus towards the mouth in a majority of the trials. Comparing the peak inbound pressures between intended and unintended use scenarios generated without the bolus, peak inbound pressure was lower under the conditions of improper mask seal. In the bolus configurations, peak inbound pressure was generally similar between the intended use and unintended use scenarios.

The outbound and inbound pressures the LifeVac device created have been characterized across a range of intended and unintended benchtop scenarios. For all intended use scenarios, the pressures developed were sufficient to move boluses representing choking hazards in 85 out of

90 trials and for all unintended use scenarios, in 338 out of 360 trials. All test configurations showed movement of the bolus towards the mouth in greater than 90% of cases and the outbound pressure was significant enough to result in a net positive movement toward the mouth as opposed to towards the lungs.

Mask Fit Analysis

The LifeVac masks (adult and pediatric) fit was further evaluated in an anthropometric data assessment. This assessment evaluated the geometric compatibility of the LifeVac pediatric and adult masks fit relative to established facial anthropometric data across pediatric and adult populations. Facial anthropometric datasets were compiled from peer-reviewed literature and publicly available databases derived from United States pediatric and adult populations. Both traditional linear measurements and three-dimensional craniofacial datasets were incorporated to characterize facial dimensions spanning from one-year-old children through adulthood. Mean facial dimensions were used for comparative analyses, with adult measurements stratified by sex and pediatric measurements based on combined male and female cohorts. The LifeVac masks dimensions within engineering tolerances were evaluated against facial anthropometry using engineering-based fit criteria. The findings from this report, in combination with the Bench and Human Factors testing, were used to inform the instructions for use with respect to the recommended mask sizes for different ages.

PERFORMANCE TESTING – CADAVER

Cadaveric testing was performed to evaluate performance of the LifeVac device on the human airway. Testing was conducted on 2 female and 1 male cadavers with no history of lung, throat, or mouth cancer or lung or throat surgery. Pre-validated simulated obstructions (boluses) were placed at the level of the larynx (at the glottic level) and the oropharynx (behind the tongue) and their positioning verified with an inspection endoscopic camera. The efficacy of the LifeVac at causing the bolus movement was investigated in three head positions: (1) Neutral, (2) Head Tilt/Chin Lift, and (3) Jaw Thrust where positions (2) and (3) were supported by a custom-made fixture.

The test was performed by using the LifeVac device on the cadaver for up to 5 times per each bolus material and bolus placement location for a total of 30 runs per cadaver in each head position. The inbound and outbound pressures generated by the device were measured using a pressure transducer placed in the oral cavity of each cadaver.

LifeVac performance was considered acceptable if greater than or equal to 50% of all test runs resulted in movement of the bolus toward the oral cavity and outbound pressure was such that the bolus did not move towards the lungs.

Consistent with the acceptance criteria, 71% of all attempts at removing the bolus resulted in movement in the direction of the oral cavity (191 out of 270 attempts). When stratified by bolus position, 70% of attempts at removing the bolus from the larynx (95 out of 135 attempts), and 71% of attempts at removing the bolus from the oropharynx (96 out of 135 attempts) resulted in

movement of the bolus in the direction of the oral cavity, respectively. All tested conditions irrespective of the head position, bolus location, and bolus type exceeded the acceptance criteria for movement of the bolus toward the oral cavity, with the exception of a neutral position. When the head was in a neutral position and the boluses were placed at the larynx, only 20% of attempts resulted in movement of the bolus in the direction of the oral cavity. When the head was in the neutral position, 51% of the attempts to remove the bolus from the oropharynx (23/45) resulted in samples reaching the oral cavity; samples from the oropharynx did not reach the oral cavity in head tilt/chin lift or jaw thrust position. No samples reached the oral cavity when attempts were made to remove the bolus from the larynx regardless of head position.

It is well known the soft tissues (i.e. muscle and connective tissue) lose strength and relax postmortem. When the cadaver head was in a neutral position, it was observed the soft tissue in the upper airway was already collapsed upon insertion of a bolus prior to the LifeVac use. No tissue collapse was observed in the head tilt/chin lift, or the jaw thrust positions as these were held by a special fixture. Accordingly, movement of the bolus in the cadavers with the neutral head position had lower success rates due to unfavorable starting conditions.

When the head was in the jaw thrust position, 27% of the attempts to remove the bolus from the oropharynx (12/45) resulted in samples moving back in the direction of the lungs. When the head was in the head tilt/ chin lift position, 7% of the attempts to remove the bolus from the oropharynx (3/45) resulted in samples moving back in the direction of the lungs. Samples did not show movement towards the lungs in the neutral position. No cadaveric samples showed movement of the bolus towards the lungs when attempts were made to remove the bolus from the larynx regardless of head position.

Soft tissue reactions including capillary burst, tissue deformation, esophageal fluid regurgitation, tissue discoloration, soft tissue abrasion, blood pooling, soft tissue laxity, and tissue reorganization were observed across the three cadaveric subjects. These possible damage modalities were noted to be minimal and did not result in any significant changes to the overall anatomy of the cadavers.

The limitations of cadaver models for choking studies need to be considered when assessing movement of the boluses towards or away from oral cavity in cadaver model. Because cadavers lack physiologic functions such as cough, gag reflex, laryngospasm, and dynamic muscle tone, they may not accurately reproduce the environments encountered in living patients during real life choking events, restricting the cadaver's ability to fully replicate the mechanics of foreign body obstruction removals. For example, movement away from the oral cavity could be due to lack of downstream pressures and tone and movement towards could be more exaggerated due to the lack of living physiological conditions.

HUMAN FACTORS TESTING

Human factors validation was performed using the subject device in simulated use scenarios to demonstrate that the LifeVac device is safe and effective for its intended use by the intended users in the intended use environments. HF testing was carried out in accordance with FDA

Guidance "Applying Human Factors and Usability Engineering to Medical Devices" (February 2016).

Two distinct user groups were identified for the LifeVac device: health care professionals (HCPs) and laypeople. Participants within each user group were randomized into either familiarized or naïve groups. The familiarized group was provided the packaged device as if they had just purchased it and asked to familiarize themselves with the device and accompanying content. This familiarization session was conducted three days prior to the simulated use testing. The naïve user group did not have any previous exposure to the device or device-user interface. No formal training was provided to either user group.

Use of the LifeVac device was assessed on either a child or adult manikin in either a seated or supine position during a simulated, high-stress choking emergency use scenario. A total of 32 HCPs were assessed with the LifeVac Travel Kit, 34 laypeople were assessed with the LifeVac Home Kit, and 16 lay people were assessed with the LifeVac Travel Kit.

Several persistent use errors and close calls were observed related to the critical tasks (e.g., not calling 911, bypassing the standard choking protocol, incorrect mask selection, not tilting the head back). Protective measures and labeling mitigations were implemented to reduce the likelihood that these use errors and problems will occur during actual use. The majority of participants were able to complete the required tasks in a manner that demonstrates no pattern of use error or difficulties were present.

The study validated that the final design of the LifeVac device and its user interface adequately meets the needs of the intended users and that all foreseeable use-related risks have been mitigated to the greatest extent possible.

SUMMARY OF CLINICAL INFORMATION

1. LifeVac Usage Reports

Two distinct cohorts from LifeVac's internal database of device use records were analyzed:

1) Per-Indications for Use (IFU) Cohort of 735 device use cases: device usage reported to LifeVac prior to 2025 through LifeVac's "Lives Saved" web survey link, requesting people who used the device to save a life to respond.

2) Per-IFU Cohort of 367 device use cases: device usage report data reported to LifeVac after January 1, 2025, though LifeVac's "Report LifeVac's Usage" web survey link.

All device usage reports were voluntarily submitted by users on the LifeVac website (https://lifevac.net/); LifeVac also shared the survey link on social media in response to success stories in 2026. Upon receipt of the case report completed on the LifeVac's website, each usage report was reviewed by LifeVac personnel, verified with the reporter by phone or e-mail and transferred into an internal database. Customer information was protected both online and offline.

The transition between the two periods (pre-2025 and post-2025) was marked by a modification to the labeling of the website portal used for reporting device usage: pre-2025, it was labeled "Report Life Saved," which encouraged the submission of usage reports with positive outcomes. In January 2025, it was relabeled "Report LifeVac Usage" in an attempt to mitigate this bias. However, LifeVac also sent this survey link to people reporting successful use of the device on social media as recently as January 2026; because of this and the self-selection that occurred in participants, results may be positively biased. Also in 2025, the question "Did the patient receive medical examination afterwards due to BLS being performed?" was changed to "Did the patient receive a medical examination afterwards?" Additionally, in February 2026, the definitions of complete obstruction and partial obstruction were added to the usage report form on the website, as 14.5% of respondents who had submitted usage reports prior to that date had reported an unknown degree of obstruction.

A study to analyze the data for these sets of usage reports was conducted by an independent Clinical Research Organization and included only those subjects who met the predefined IFU (Indications for Use) inclusion criteria.

- Inclusion:
    - Choking event occurred in the United States
    - Per IFU
        - Choking victims with complete obstruction
        - Food or object as the choking substance
        - Adherence to current BLS protocols prior to device use, and
        - Age of choking victim one year or older
    - LifeVac Device was used in a choking event
- Exclusion Criteria
    - Non-U.S. cases
    - No data on patient age
    - Not per IFU

The main objectives of the study were to assess the safety and effectiveness of the device based on the following primary endpoints:

1. <u>Safety Endpoints:</u>
    (i) Primary Safety Endpoint: Any adverse events associated with the choking incident and use of the device as reported, or noted during verification, were reviewed. The primary safety endpoint was the occurrence of any serious adverse events (SAE) associated with the use of the LifeVac device.
    (ii) Secondary Safety Endpoint: All adverse events reported, or noted during verification, were reviewed and determined whether associated with the use of the device or procedure. All adverse events (AE) are discussed for the secondary safety endpoint.

2. <u>Effectiveness Endpoints</u>:
    (i) Primary Effectiveness Endpoint: Determination of effectiveness was done by counting the numbers of success or partial success out of the total number of reported

use cases. The statistical analysis included calculations of confidence interval of the device effectiveness using the definitions of success/partial success.

(ii) Secondary Effectiveness Endpoint: The study explored potential correlations between the outcome of the device use with age of the choking person, the nature of the obstruction, and other subgroups.

Success was defined as: Obstruction removed and breathing restored following use of the device, without further intervention required.

Partial Success was defined as: Obstruction removed and breathing restored following use of the device; however, further intervention (additional BLS measures, finger sweep of the oral cavity, coughing, swallowing, or vomiting) was necessary to remove the obstruction.

Failure was defined as: Obstruction was removed and breathing was restored following surgical intervention / hospitalization, obstruction was not removed, or breathing was not restored (i.e., death).

The methods for data processing, definition of clinical endpoints for the two analyses were the same.

A. Pre-2025 Per-IFU Cohort:

LifeVac collected 2,930 cases of LifeVac device uses, reported to LifeVac between 2014 and January 2025 through the website portal labeled "Report Life Saved." Of these cases, the "Per IFU" group included 735 cases that met the inclusion/exclusion criteria. All 735 cases were included in the safety analysis and 681 cases were included in the effectiveness analysis (cases in which outcome was known). **Note that this data is likely positively biased because it is only from device users who reported using the device successfully.**

STUDY RESULTS:

Primary Safety Analysis

Of the 735 reported device use cases used in the safety analysis, results showed only 23 cases reported serious adverse event (SAE) related to the choking incident (i.e., aspiration pneumonia, injuries to the airway, broken ribs due to basic life support, other internal injuries, bleeding, death, or other SAE). See Table 1 below. **Note that this data is likely positively biased because it is only from device users who reported using the device successfully.**

Table 1: SAE Counts (23/735) for Pre-2025 Per-IFU Cohort

Adverse Event	Count

Overall SAE	**23**
Throat damage	3
Broken ribs due to basic life support	8
Bleeding	1
Aspiration pneumonia	3
Ventilator	1
Coma	1
Death	6

Secondary Safety Analysis

Of the 735 reported device use cases, there were a total of 34 AEs of which 15 reported AEs for device related complications and 19 reported AEs for choking related complications .

Of the 15 AEs reported for device related complications, the AEs most frequently documented were abrasions of the mouth or throat (N=8). Four patients reported bruising of the nose or mouth, two patients reported bleeding, and one patient reported swelling of airway.

Of the 19 AEs reported for choking related complications, 15 cases were of throat irritation and four cases that were reported as "other" and included: two cases of broken vessels around the eye and on the chest from BLS measures, one case of sore stomach and back, one case of red petechiae spots in the mouth due to low oxygen.

Primary Effectiveness Analysis

Of the 735 device use cases reported in the LifeVac database, 681 device use cases (93%) were considered for the effectiveness analysis (i.e., effectiveness cohort). Success or partial success was recorded in 654 cases. **Note that this data is likely positively biased because it is only from device users who reported using the device successfully.**

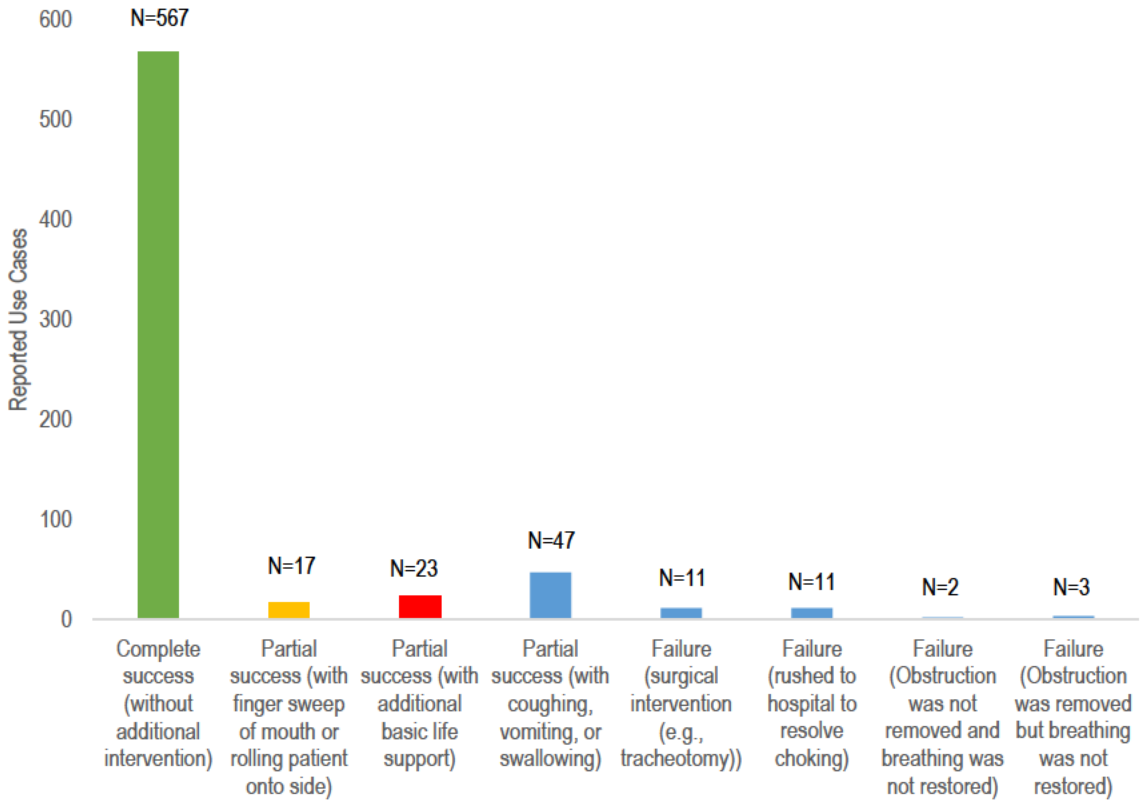
Table 2. Primary Effectiveness for Pre-2025 Per-IFU Cohort

Outcome	N
Overall success (Complete + Partial)	654

Complete Success	567
Partial Success	87
Failure	27

Reference Figure 4 for a graphical representation of LifeVac use outcomes. Overall, the data reflects a majority of successful outcomes, with minimal instances of adverse or fatal events.

Figure 4. Outcomes of using the LifeVac device (N=681) for Pre-2025 Per-IFU Cohort



B. Post-2025 Per-IFU Cohort

LifeVac collected 1,681 cases of LifeVac device uses, reported to LifeVac between February 1, 2025 and November 14, 2025 following change of language on the LifeVac website ("Report LifeVac Usage"). LifeVac also sent this survey link to people reporting successful use of the device on social media as recently as January 2026. Of these cases, the "Per IFU" group included 367 cases that met the inclusion/exclusion criteria. All 367 cases were included in the safety analysis and 319 cases were included in the effectiveness analysis (cases with known outcome).

Note that this data is likely positively biased because of the self-selection that occurred in participants.

STUDY RESULTS:

Primary Safety Analysis

Of the 367 reported device use cases used in the safety analysis, results showed 30/367 cases of reported serious adverse event (SAE) related to the choking incident (i.e., aspiration pneumonia, injuries to the airway, broken ribs due to basic life support, other internal injuries, bleeding, death, or other SAE).

Table 3. SAE Counts (30/367) for Post-2025 Per-IFU Cohort

Adverse Event	Count
Overall SAE	**30**
Throat damage	5
Hiatal hernia	1
Cardiac arrest/stress	4
Sepsis	1
Aspiration pneumonia	9
Brain Damage	1
Death	9

Secondary Safety Analysis

Of the 367 reported device use cases, there were a total of 26 AEs of which 12 reported AEs for device related complications and 14 reported AEs for choking related complications.

Of the 12 AEs reported for device related complications, the AEs most frequently documented were abrasions of the mouth or throat (N=8). One patient reported bruising of the nose or mouth and three patients reported "Other" complications: 2 broken blood vessels around the eye and one reported hoarse voice.

Of the 14 AE reported for choking related complications, five included throat irritation and nine reported "Other" complications including one hoarse voice, seven cases of wheezing, shortness of breath, or low oxygen and two cases of broken blood vessels around eye.

Primary Effectiveness Analysis

Of the 367 device use cases reported in the LifeVac database, 48 were excluded from effectiveness analysis due to "unknown" outcome. The remaining 319 device use cases were considered for the effectiveness analysis (i.e., effectiveness cohort).

Based on the outcomes reported by the 319 device use cases considered for the effectiveness analysis, success or partial success was recorded in 307 cases .

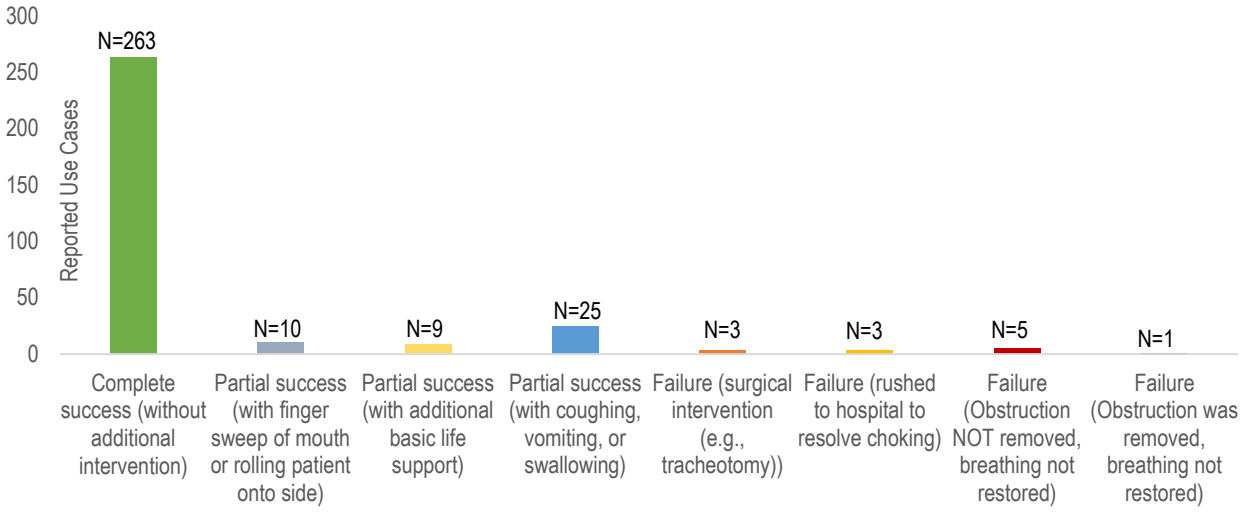
Table 4. Primary Effectiveness for Post-2025 Per-IFU Cohort

Outcome	N
Overall success (Complete + Partial)	307
Complete Success	263
Partial Success	44
Failure	12

However, these results may be positively biased due to LifeVac's outreach to individuals who shared success stories online to complete the survey, and due to self-selection bias in survey respondents (people with a good experience using the device being more likely to proactively seek out the opportunity to complete the survey).

Reference Figure 5 for a graphical representation of LifeVac use outcomes. Overall, the data reflects a majority of successful outcomes, with minimal instances of adverse or fatal events.

Figure 5. Outcomes of using the LifeVac device (N=319) for Post-2025 Per-IFU Cohort



2. LifeVac Purchasers Survey Study

This was an observational, non-interventional survey study conducted on purchasers of the LifeVac device. The study was conducted by an independent Clinical Research Organization. Survey invitations were sent to 100,000 purchasers of the product who were randomly selected from a database of people who had purchased LifeVac. Participants were invited by e-mail to take part in the study survey hosted on a digital platform. Participants who have used the device had to answer a comprehensive survey, delving into specifics of the choking incident.
The study inclusion criteria, safety and effectiveness endpoints were as follows:

Inclusion Criteria

- Purchasers of the LifeVac device
- English speaking
- Ability to understand and accept the HIPAA waiver/Consent form
- Per-IFU Group
    - Complete obstruction
    - Food or object as obstruction
    - BLS Performed prior to use
    - Choking patient age one year or older

Safety Endpoints

(i) Primary Safety Endpoint: Any adverse events associated with the choking incident and use of the device were collected as part of the survey. The primary safety endpoint was the occurrence of any significant adverse events (SAE) associated with the use of the LifeVac device.

(ii) Secondary Safety Endpoint: Any adverse events associated with the choking incident and use of the device were collected as part of the survey. The secondary safety endpoint was the occurrence of any adverse events (AE) associated with the use of the LifeVac device.

Effectiveness Endpoints

(i) Primary Effectiveness Endpoint: Determination of effectiveness endpoints was done by counting the numbers of success or partial success out of the total number of reported use cases. The objective of the analysis was to confirm success or partial success in at least 80% of uses of the device.
(ii) Secondary Effectiveness Endpoint: The study explored potential correlations between the outcome of the device use with age of the choking person, the nature of the obstruction, environment where the choking incident transpired, and the device user's experience.

STUDY RESULTS:

Of the 100,000 LifeVac device purchasers who received the survey emails, 1,414 (1.4%) purchasers opened the survey link, 694 purchasers (0.7%) accepted the HIPPA waiver/Consent form, and 639 purchasers (0.64%) completed the survey. 617 purchasers (96.5% of responders) reported the LifeVac device was not used while 22 purchasers (3.5%) reported use of the LifeVac device. Of the 22 device uses, 6 cases were determined to be per IFU, and 3 of the 6 were previously reported to LifeVac through usage reports. Based on the extremely limited sample size, meaningful inferences cannot be drawn from the survey results.

Safety Summary

- *Medical Care Following LifeVac Use:* In 3 cases out of 6 per IFU, no further medical care was required after using the LifeVac device in a choking incident. In the other 3 instances, EMS was called, and in two of those cases the choking patients were also taken to the emergency room, and one of those instances, the choking person was admitted to the hospital.
- *Medical Complications Related to LifeVac Device:* Of the 6 cases per IFU, 5 said none in regard to complications related to the LifeVac device and 1 said unknown.
- *Medical Complications Related to Choking Incident:* In three cases of the 6 per IFU, there were no complications reported related to the choking incident. In three cases, throat irritation was reported.
- *SAE:* No severe adverse events (e.g., injuries to the airway, broken ribs due to BLS, other internal injuries, brain damage, death, or other) were reported in the 6 cases per IFU.

Effectiveness Summary

Based on the outcomes reported by the six device use cases considered for the effectiveness analysis, success or partial success was recorded in five cases.

- Successful use of the device (defined as "obstruction was removed and normal breathing restored with no further intervention") was reported in one of the cases.
- Partial success (defined as "obstruction was removed and normal breathing restored with a simple finger swipe of the patient's mouth, and/or rolling the patient onto their side, and/or additional BLS measures") was reported in four of the cases.

- Failure (defined as either "obstruction being removed and normal breathing restored only after surgical intervention" or hospitalization, or obstruction was not removed and breathing was not restored") was reported in one case.

Summary of Clinical Evidence and Conclusions

These findings from all three datasets (summarized above) suggest benefit with few reported adverse events. However, there are several limitations to these datasets. The sample size of device users who used the device according to the IFU is too small to draw conclusions from about the rates of success and the rates of adverse events occurring. The datasets were derived from voluntary reporting, which inherently introduces the potential for selection/reporting bias. The data included responses from witnesses, though it is unclear whether the witnesses were close enough to the incident and remained on scene for the entire incident to accurately report on the incident. Additionally, individuals with particularly favorable or unfavorable experiences may be more likely to respond than others. The data also suffers from recall bias, as most participants reported on events that occurred over a month prior.

Pediatric Extrapolation:

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population. The device is indicated for pediatric patients over 1 year old and those patients were included in the clinical information provided.

POSTMARKET SURVEILLANCE

LifeVac will collect and report post-market surveillance data acquired under anticipated conditions of use to demonstrate that the device performs as intended in the intended patient population. Specifically, LifeVac will conduct post-market surveillance of the LifeVac, with a justified sample size, as outlined below:

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

LABELING AND TRAINING

The labeling consists of the following, which are located within the device packaging:

- Information Page
- Instructions for Use (also printed externally on the primary packaging)

- On-product yellow IFU hangtag (directly on the device)
- Practice Instructions (with Practice Mask, included in the Home Kit only).

Labeling for this device is in accordance with the special controls listed below.

Training is provided in the form of a training video, which is located on the website. A QR code linking directly to the training video is located in various locations on the labeling, including on the outer packaging, Information Page, and Instructions for Use. On conclusion of viewing the video, the user will be brought back to the website for a certification quiz to allow user to self-assess understanding of the device and its instructions for use.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the suction anti-choking device as a second-line treatment and the measures necessary to mitigate these risks.

Table 5. Summary of Risks and Mitigations

Identified Risks to Health	Mitigation Measures
Injury or death from choking • 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 • 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

SPECIAL CONTROLS

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.

BENEFIT/RISK DETERMINATION

Choking is a life-threatening condition that progresses rapidly, leading to devastating complications often before medical attention is available. Within 2 minutes of complete obstruction, oxygen saturation falls with subsequent unconsciousness. Currently, BLS interventions (5 back blows/5 abdominal thrusts or chest thrusts) have a success rate of about 75%.[1,2] If unsuccessful, victims can rapidly progress to unresponsiveness, respiratory arrest, and death. In many communities, the average response time in the US for advanced medical services is approximately 7 to 10 minutes.[3] LifeVac is designed to enable immediate intervention at the point of emergency, allowing an individual to attempt airway clearance prior to the arrival of advanced medical care and thereby helping to address the critical time gap between failed rescue maneuvers and definitive medical management.

For an unconscious victim, if CPR cannot generate effective breaths, LifeVac is an option to remove the obstruction. Although the use of the LifeVac does delay CPR by 1.5 minutes, CPR is not effective if breaths are not delivered, and only 33% of lay people trained in CPR can perform effective CPR.[4]

The limited data based on the sponsor's database and published studies suggests benefit with few adverse events. The sponsor's internal databases of self-selected respondents to surveys, including the "Report Life Saved" and "Report LifeVac Usage," indicated that there were users who were able to use the device to successfully to resolve choking. In addition, in a survey emailed to device purchasers, out of the 6 respondents reporting using the device per the Indications for Use, 5 of them reported full or partial success.
Reported adverse events and complications were minor and were reported as abrasions of the mouth or throat, bruising of the nose or mouth and bleeding. There were no reported serious adverse events (SAEs) related to the device. Review of Medical Device Reports (MDRs) only revealed one verified case related to a patient.

Bench testing showed that regardless of the airway size and use scenarios, LifeVac was able to generate inbound pressure sufficient to move the bolus towards the mouth. Cadaver testing demonstrates proximal movement of validated test articles, although not complete extraction. A partial relief of obstruction may still be beneficial, as respiration continues without respiratory arrest, and this allows time for the patient to be treated by medical personnel.

Human factors testing supports the use of the device by laypersons and medical professionals. Human factors testing revealed that users can assemble and use the device within 169 seconds. The time to perform the standard choking protocol plus the time for assembly and use of the LifeVac fall within the 240 seconds (4 minute) window when permanent brain damage due to hypoxia starts to develop. While several persistent use errors and close calls were observed related to the critical tasks (e.g., not calling 911, bypassing the standard choking protocol, incorrect mask selection, not tilting the head back), protective measures and labeling mitigations were implemented to reduce the likelihood that these use errors and problems will occur during actual use. The majority of participants were able to complete the required tasks in a manner that demonstrates no pattern of use error or difficulties were present.

Based on the totality of the information provided, including the survey data, non-clinical data, and human factors data, there is sufficient evidence to support concluding that the probable

benefit of LifeVac exceeds the probable risks, for its use in the resolution of complete airway obstruction as a second line treatment for choking. However, there is remaining uncertainty that the risks and benefits are not fully characterized. Specifically, it is uncertain whether: (1) using LifeVac may result in the user delaying or not using the BLS choking protocol; (2) LifeVac may be used on patients for whom the device is not indicated; and, (3) LifeVac successfully resolves choking in the real-world scenario. Therefore, monitoring of device use risks, safety events, and effectiveness are necessary via post-market surveillance. This information will be used to improve device labeling and potentially other Agency communications, as necessary, about the real-world benefits and risks of these devices.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

> 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.

The probable benefits outweigh the probable risks for the LifeVac device. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the LifeVac is granted and the device is classified as follows:

> Product Code: QXN
> Device Type: Suction anti-choking device as a second-line treatment
> Regulation Number: 21 CFR 874.5400
> Class: II

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