EMERGO GROUP

LifeVac – Class I Medical Device

SYSTEMATIC LITERATURE REVIEW AND CLINICAL EVALUATION REPORT (TO ADDRESS THE REQUIREMENT FOR CLINICAL EVIDENCE OF SAFETY AND PERFORMANCE)

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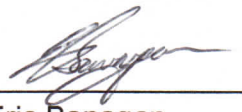

9/3/15

Eric Banagan — Date
Managing Director
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Statement on Clinical Data Used to Affix CE Marking

This clinical evaluation report is intended to address the requirements of Directive 93/42/EEC, as amended by Directive 2007/47/EC, for clinical evidence of the safety and effectiveness of a medical device.

The clinical evaluation report has been prepared in accordance with:

a) European Commission guidance published in MEDDEV 2.7.1 rev.3 (December 2009), Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies; and,
b) Annex A of ISO 14155: 2011, Clinical investigation of medical devices for human subjects – Goods clinical practice.

Clinical evaluation of the LifeVac device is based on an assessment of the risks and benefits associated with the clinical use of anti-choking devices, presented in the form of a documented critical review of available relevant scientific literature concerning clinical experience with the use of anti-choking devices and in the form of a documented review of post market experience concerning the use of anti-choking devices and also the sales and complaints history relating to the LifeVac device.

1. OBJECTIVE OF THE CLINICAL EVALUATION REPORT

The objective of this report is to provide a documented evaluation of the available evidence of the clinical performance and safety of the LifeVac device, for conformity with the clinical data requirements of Directive 93/42/EEC, as amended by Directive 2007/47/EC.

Conformity assessment with Directive 93/42/EEC, as amended by Directive 2007/47/EC, requires LifeVac Europe Ltd - as the manufacturer of the LifeVac device - to demonstrate that the claims made in relation to the product's safety and performance, under the normal conditions of use, are achieved, and that the clinical benefits associated with use of the device outweighs any clinical risks. Typically, this requires clinical data (Annex X, §1.1 of the Directive). Annex X of the Directive allows that evidence of the satisfactory clinical safety and performance of a device may be provided in the form of a critical evaluation of published and / or unpublished data on the device, or on a similar device for which equivalence can be demonstrated.

Evaluation of the clinical performance and safety of the LifeVac device was performed through a systematic search and critical review of unpublished and published clinical data concerning the use of anti-choking devices and in the form of a documented review of post market experience concerning the use of anti-choking devices and also the sales and complaints history relating to the LifeVac device.

2. DESCRIPTION OF THE DEVICE

LifeVac is a non-powered single suction apparatus designed to save the life of a choking victim. The device is made up of two components; these being a handle and face mask. Three face masks are supplied in total; two medium and one small - one medium face mask is intended for product orientation.

The device is made up of two components; a handle and a face mask. The handle is manufactured from polypropylene and the face masks are manufactured from polyethylene and PVC. A Product Data sheet for the face masks which is the skin contacting part of the device; can be located in Appendix F of this technical file.

The LifeVac device is intended to be used by laypersons outside a healthcare environment.

LifeVac is a single use device and is supplied non-sterile.

An individual unit is packed into a cardboard box along with 3 face masks and relevant literature including an Instruction for Use leaflet.

The LifeVac device is to be CE Marked in Europe as a Class I medical device, under Rule 1.

3. SUMMARY OF RISK ANALYSIS

A risk analysis has been conducted for the LifeVac device, which complies with EN ISO 14971:2012. The output from the risk analysis was a documented risk management report, which is included in the technical documentation for this device. The risk management report identifies all of the known and anticipated clinical risks associated with the use of these devices.

The principal clinical risks associated with the use of the LifeVac device are that:

- The LifeVac device will not achieve the manufacturer's claims in respect of performance; and,
- The use of the LifeVac device will result in an unacceptable toxicological reaction.

4. MATURITY OF THE TECHNOLOGY UNDER REVIEW

The LifeVac device is a new innovation and as such there is very little data available in respect of the device itself; or equivalent devices.

LifeVac is a non-powered single suction apparatus designed to save the life of a choking victim. A search was carried out to assess what medical devices were available with the same intended use to that of the LifeVac device, only one device came up during the search – details of which can be located in section 5 of this report.

The device is made up of two components; a handle and a face mask. The handle is manufactured from polypropylene and the face masks are manufactured from polyethylene and PVC. Polypropylene, polyethylene and PVC have been used in a variety of medical device applications where the intended use involves contact with intact skin and have been available for many years within the medical industry.

5. RELEVANT EQUIVALENT DEVICES

There is one anti-choking device currently marketed which is similar to the LifeVac device in terms of its intended use, and indications for use. It is commercially available in Europe, details as follows:

- ActFast Med Anti Choking Trainer

The ActFast Med Anti Choking Trainer has been commercially available since 2009.

6. METHODOLOGY FOR SYSTEMATIC LITERATURE SEARCH / SELECTION

6.1 Search Methodology

6.1.1 Bibliographic database searches

Electronic searches of PUBMED / Medline bibliographic databases and the internet were performed in March 2015 using the following search terms:

- Anti-choking device
- LifeVac
- ActFast Med Anti Choking Trainer

Limits applied were:

- English language articles only

6.1.2 Assessment of results from systematic literature search

Published papers identified from electronic searches of bibliographic databases were first screened for inclusion in this critical literature review on the basis of their titles and abstracts. Full text copies were obtained for all articles that passed this initial screen, and also for those whose relevance was not immediately evident from initial screening. Screening of search results, article abstracts and of full texts was performed by Emergo Group's Regulatory Consultant.

6.1.3 Data inclusion and exclusion criteria

The results returned from searches of the literature sources were screened on the basis of their titles and abstracts to identify whether the information was relevant to the LifeVac device. Full text copies were obtained of all the papers that passed the initial screen and of those whose relevance was not immediately obvious from the abstract. The full text was reviewed for inclusion. The reviewer was not blinded by names of authors, or institutions, or journals, or the outcomes of the trial. Data was assessed with respect to its possible contribution and weighting in establishing both the performance and safety of the device. Screening of search results, article abstracts and of full texts was performed by Emergo Group's Regulatory Consultant.

7. RESULTS OF SYSTEMATIC LITERATURE SEARCH / SELECTION

The searches of the two bibliographic databases using the search terms described above returned a total of 87 citations (including duplications) concerning the use of anti-choking devices, made up of the following individual search results:

Search no.	Search term	No. of articles
1	Anti-choking device	86
2	LifeVac	1
3	ActFast Med Anti Choking Trainer	0

After screening the papers in the light of the inclusion and exclusion criteria, and removal of duplicate and non-relevant papers, no papers reporting on the use of anti-choking devices or equivalent devices for a similar intended purpose were found for inclusion in the report.

8. POST MARKET SURVEILLANCE

LifeVac has been on the market since September 2014. To date, there have been no reportable incidents to the MHRA or FDA and no customer complaints have been reported.

LifeVac Europe Ltd also has a post market surveillance procedure in place. The procedure details the methods used by LifeVac Europe Ltd for conducting post-market surveillance of the company's medical devices marketed in Europe.

To date there have been no adverse events or recalls relating to the ActFast Med Anti Choking Trainer; reportable to the MHRA who publishes details of safety issues on its website affecting devices sold in the UK in the form of medical device alerts, field safety notices and safety letters.

The FDA website was reviewed to see if there had been any adverse events or recalls of the ActFast Med Anti Choking Trainer. The FDA publishes details of safety issues on its website (Manufacturer and User Facility Device Experience (MAUDE) database). A search was carried out for the period 01/01/2010 to date – there were no adverse incidents reported during this time.

9. CRITICAL EVALUATION OF POST-MARKET SALES VS COMPLAINT DATA

9.1 Evaluation of the risk that LifeVac Europe Ltd's – LifeVac device will not achieve the manufacturer's claims for performance in respect of the intended use

LifeVac Europe Ltd has a Customer Complaints procedure in place. In the event that a complaint is received from an end-user at the LifeVac Europe Ltd facility, details of the complaint are noted and an investigation is launched. All findings are reported to the complainant. Depending on the nature of the complaint, the supplier who manufactured the component (handle or face mask) may be contacted and provided with details of the complaint. If necessary, the supplier launches an investigation into the complaint and findings are reported to LifeVac Europe Ltd, who in turn reports the findings to the end user.

Records relating to customer complaints are filed at the LifeVac Europe Ltd facility. They are reviewed on a regular basis. The aim is to ensure there are no emerging trends that in turn could lead to an adverse incident.

9.2 Evaluation of the risk that the LifeVac Europe Ltd's – LifeVac device may cause unacceptable toxicological reaction in the clinical setting

The biological safety of the LifeVac device has been evaluated in accordance with ISO 10993-1: 2009. Under this standard, for the stated intended use; the patient contacting component (face masks) are classified as non-contacting devices. As such, the biological safety tests that required consideration were:

- Cytotoxicity
- Sensitization
- Irritation / intracutaneous reactivity

Biocompatibility testing has been undertaken in respect of the face masks, copies of the reports can be located in the LifeVac devices' technical file.

In respect of the non-patient contacting component (handle), in accordance with EN ISO 10993-1: 2009, medical devices that do not contact the patient's body directly or indirectly are not included in the scope of EN ISO 10993, as such no biological safety tests are recommended for the handle component of the LifeVac device.

Taking the above into consideration, it is considered that the risk of the LifeVac Europe Ltd – LifeVac device eliciting an unacceptable biological response, when used as directed by the manufacturer, is appropriately controlled and that no further testing is necessary to satisfy ISO 10993-1: 2009.

10. CONCLUSION

In respect of the requirement in Directive 93/42/EEC, as amended by Directive 2007/47/EC, for clinical evidence to be provided of the safety and effectiveness of the LifeVac device, given that there have been no complaints or serious adverts reported to the MHRA and FDA and taking into account biocompatibility testing has been carried out on the patient contacting component; it is considered that Essential Requirement 14 of Directive 93/42/EEC, as amended by Directive 2007/47/EC has been satisfied in respect of the manufacturer's claims relating to the clinical safety and performance of the device, as a result of this, a clinical investigation to evaluate the performance is not required. Accordingly, it is concluded that the risk of the LifeVac device failing to achieve acceptable levels of clinical performance and safety; is very low and is outweighed by the clinical benefit of using the LifeVac device.

On this basis, the requirements of Directive 93/42/EEC, as amended by Directive 2007/47/EC, for clinical evidence of the safety and performance of the LifeVac Europe Ltd – LifeVac device are considered to be satisfied.

11. BIBLIOGRAPGHY

Papers returned from the literature search

11.1 Pubmed Search (indexed for MEDLINE) – Anti choking device (86)

1 – 86: Refer to Appendix I of this Clinical Evaluation Report.

11.2 Pubmed Search (indexed for MEDLINE) – LifeVac (1)

87: Beau P, Matrat S. A comparative study of polyurethane and silicone cuffed-catheters in long-term home total parenteral nutrition patients. Clin Nutr. 1999 Jun;18(3):175-7.

11.3 Pubmed Search (indexed for MEDLINE) – ActFast Med Anti Choking Trainer (0)