Guidance for Industry and FDA Reviewers

Class II Special Control Guidance Document for Acute Upper Airway Obstruction Devices

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Circulatory Support and Prosthetics Devices Branch
Division of Cardiovascular, Respiratory, and Neurological Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Michael Husband, Center for Devices and Radiological Health, HFZ-450, 9200 Corporate Blvd, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Michael Husband at 240-276-3700.

Additional Copies

World Wide Web/CDRH/ home page at http://www.fda.gov/cdrh/ode/guidance/1138.pdf or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1138 when prompted for the document shelf number.

Class II Special Control Guidance[1] Document for Acute Upper Airway Obstruction Devices

Background

On February 29, 2000, FDA classified Acute Upper Airway Obstruction Devices from Class III designation to Class II and exempted them from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act. This guidance document describes a means by which acute upper airway obstruction devices may comply with the requirement of class II special controls. Designation of this guidance document as a special control means that manufacturers of Acute Upper Airway Obstruction Devices that follow the recommendations listed in this document before introducing their device into commercial distribution in the United States will be able to market their device. Manufacturers must maintain in their device master records and be able to demonstrate that their specific device complies with either the recommendations of this guidance or some alternate means that provides equivalent assurance of safety and effectiveness. If the manufacturer cannot comply with either of the above, they will not be exempt from the requirements of premarket notification and will need to submit a premarket notification submission and receive clearance prior to marketing.

[1]This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Scope

FDA identifies an acute upper airway obstruction device as a raised rounded pad that is intended for use in relief of choking in acute upper airway obstruction in victims who weigh approximately 80 pounds or more. This generic type of device is an anesthesiology device classified under 21 CFR 868.5115, product code MZT. It is for over-the-counter use and, in the event of choking on a foreign body, can be applied to the abdomen and pushed upward to generate expulsion pressure to remove the obstruction.

Risks to Health

FDA has identified two risks to health associated with this type of device. These risks involve: 1) incorrect use resulting in damage to the internal organs of the thorax and/or the abdomen, and 2) faulty device design that generates and applies too much pressure to the abdomen resulting in patient injury.

Special Controls Guidance

FDA believes the following controls, when combined with the general controls of the act, will provide reasonable assurance of the safety and effectiveness of this type device: Labeling that includes instructions for reporting complications resulting from the use of the device directly to the manufacturer, as well as any applicable medical device reporting requirements (21 CFR 803).

1. Labeling for the lay user that includes adequate instructions for use including (i) a clear identification of the minimum victim size threshold (weight), as well as any device-specific limitations identified through application of design controls and (ii) instructions for use of the Heimlich maneuver.

2. Design controls that satisfactorily evaluate:

- the potential for excessive generation and application of pressure to the abdomen that can result in damage to the internal organs. The generated pressures and their distributions over the abdomen should be assessed for safety and compared to the Heimlich maneuver in a variety of victim sizes and user strengths;

- the initial and peak airway pressures and the duration of pressure application of the device as compared to the Heimlich maneuver;

- bench testing to include static load, mechanical shock, fatigue and intraabdominal pressure simulation; and

- human factors testing to demonstrate that the lay user is able to understand and follow the device instructions for use with respect to device placement and applied force. The testing should include a range of rescuers' sizes, ages and educational levels, as well as an appropriate range of victim size and position.

Premarket Notification Requirements

Section 510 (m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of this generic type of device. Thus, persons who intend to market a device of this type do not need to submit a premarket

notification to FDA and receive agency clearance prior to marketing the device, but must comply with the general and special controls.

Limitations of Exemption from Premarket Notification

FDA's decision to grant an exemption from the requirement of premarket notification for a generic type of class II device is based upon the existing and reasonable foreseeable characteristics of the commercially distributed devices within that generic type. In 21 CFR 868.9, you will find specific limitations on this exemption for this type device. If you exceed the limitations, you must submit a premarket notification.