

97-46 in the **Federal Register** (62 FR 30378) on June 3, 1997.

Raymond W. Kelly,
Commissioner of Customs.

Approved: June 19, 2000.

John P. Simpson,
Deputy Assistant Secretary of the Treasury.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. 00P-1117]

Medical Devices; Anesthesiology Devices; Classification of Devices to Relieve Upper Airway Obstruction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying devices to relieve upper airway obstruction into class II (special controls). The special control that will apply to this device is a labeling and design control guidance document. This action is being taken in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). The agency is classifying this device into class II in order to provide a reasonable assurance of the safety and effectiveness of the device.

DATES: This rule is effective July 24, 2000.

FOR FURTHER INFORMATION CONTACT: Carroll O'Neill, Center for Devices and Radiological Health (CDRH) (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8262, ext. 170.

SUPPLEMENTARY INFORMATION:

I. Background

The act, as amended by the amendments (Public Law 94-295), the SMDA (Public Law 101-629), and FDAMA (Public Law 105-115), establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) establishes three categories (classes) of devices,

depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(f)(1) of the act, devices that were not in commercial distribution before May 28, 1976, the date of enactment of the amendments, generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or class II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the FDA regulations (21 CFR part 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device by written order. 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 such classification.

In accordance with section 513(f)(1) of the act, FDA issued an order on December 29, 1999, classifying the Quickair Choke Reliever, Model 59-001A in class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. On December 20, 1999, FDA filed a petition from Maet, Industries, Inc., requesting classification of the device into class II under section 513(f)(2) of the act.

After review of the information submitted in the petition, FDA determined that the Quickair Choke Reliever, Model 59-001A can be

classified in class II with the establishment of special controls. FDA believes that class II special controls, in addition to the general controls, provide reasonable assurance of the safety and effectiveness of the device. On February 29, 2000, FDA issued an order to the petitioner classifying the Quickair Choke Reliever, Model 59-001A, and substantially equivalent devices of this generic type into class II under the generic name, "Devices to relieve upper airway acute obstruction." In addition to the general controls of the act, the Quickair Choke Reliever, Model 59-001A is subject to the following special control: "Class II Special Control Guidance Document for Acute Upper Airway Obstruction Devices." The guidance document covers:

(1) 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 part 803).

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

(3) Design controls that satisfactorily evaluate:

(a) The potential for excessive generation and application of pressure to the abdomen that can result in damage to the internal organs;

(b) The generated pressures and their distributions over the abdomen as compared to the Heimlich maneuver in a variety of victim sizes and user strengths;

(c) The initial and peak airway pressures and the duration of pressure application of the device as compared to the Heimlich maneuver;

(d) Bench testing to include static load, mechanical shock, fatigue and intra-abdominal pressure simulation; and

(e) 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 rescuer's sizes, ages and educational levels, as well as an appropriate range of victim size and position.

In order to receive the document entitled "Class II Special Control Guidance Document for Acute Upper Airway Obstruction Devices" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381

or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system and then enter the document number 1138 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the document entitled "Guidance on 510(k) Submissions for Acute Upper Airway Obstruction Devices," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. The document entitled "Guidance on 510(k) Submissions for Acute Upper Airway Obstruction Devices" will be available at <http://www.fda.gov/cdrh/ggpmain.html#docs>.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is exempt from the premarket notification requirements. FDA believes that the special controls are adequate to provide reasonable assurance of the safety and effectiveness of the device. Thus, persons who intend to market a device of this type do not need to submit to FDA a premarket notification and receive agency clearance before marketing the device.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866

and the Regulatory Flexibility Act (5 U.S.C. 601-612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104-121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency knows of only one manufacturer of this device. Without this rule, the manufacturer would be required to obtain approval of a premarket approval application from FDA before marketing this device. Therefore, this rule reduces an economic burden for this manufacturer and any future manufacturers of this type of device. The agency, therefore, certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted for inflation.

IV. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not

contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 868

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 868 is amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

1. The authority citation for 21 CFR part 868 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 868.5115 is added to subpart F to read as follows:

§ 868.5115 Device to relieve acute upper airway obstruction.

(a) *Identification.* The device is a raised, rounded pad that, 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 to relieve acute upper airway obstruction.

(b) *Classification.* Class II (special controls) ("Class II Special Control Guidance Document for Acute Upper Airway Obstruction Devices").

Dated: June 13, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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