



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 29 2000

Mr. Michael Chao  
Maet Industries, Inc.  
4215 Renoak Court  
Mississauga, Ontario  
Canada

Re: K993284- Evaluation of Automatic Class III Designation  
Device Name: Quickair Choke Reliever, Model 59-001A  
Classification Regulation: 21 CFR 868.5115  
Regulatory Class: Class II, Exempt from Premarket Notification  
Requirements  
Product Code: MZT

Dear Mr. Chao:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the Quickair Choke Reliever, Model 59-001A, that is intended for use in relief of choking in acute upper airway obstruction in victims who weigh approximately 80 pounds or more. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II, exempt from premarket notification. This order, therefore, classifies the Quickair Choke Reliever, and substantially equivalent devices of this generic type into class II under the generic name, *Devices to Relieve Acute Upper Airway Obstruction*.

FDA identifies this generic type of device as an anesthesiology device under 21 CFR 868.5115. This generic type of device is for over the counter use and consists of 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.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (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 II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act

(21 U.S.C. 360c(i)), 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 807). Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device 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. 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** classifying the device.

On January 28, 2000, FDA filed your petition requesting classification of the Quickair Choke Reliever into class I or II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on December 29, 1999 automatically classifying the Quickair Choke Reliever in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the Quickair Choke Reliever 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 petition, FDA has determined that the Quickair Choke Reliever, intended in the event of choking to remove a foreign body airway obstruction through generation of expulsion pressure, can be classified in class II with the establishment of special controls. FDA believes that special controls, when combined with general controls, in particular the design control requirements outlined in 21 CFR 820.30, provide reasonable assurance of the safety and effectiveness of the device.

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. Therefore, the Quickair Choke Reliever is subject to the following special controls which when combined with the general controls of the act, will provide reasonable assurance of the safety and effectiveness of the device:

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 803).

2. 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.
3. 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 rescuer's sizes, ages and educational levels, as well as an appropriate range of victim size and position.

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, if 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, and therefore, the device type is exempt from the premarket notification requirements. 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.

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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

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As a result of this order, you may immediately market this device, subject to the general control provisions of the act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Carroll O'Neill at (301) 443-8262 extension 170.

Sincerely,

A handwritten signature in cursive script that reads "Philip J. Phillips". The signature is written in black ink and is positioned above the typed name.

Philip J. Phillips  
Deputy Director for Science and  
Regulatory Policy  
Office of Device Evaluation  
Center for Devices and  
Radiological Health