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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; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of June 23, 2000 (65 FR 39098). The document classified devices to relieve acute upper airway obstruction. These type devices were classified into class II. The preamble to the final rule correctly states that the devices were exempt from premarket notification, but this exemption was not reflected in the regulatory text. This document corrects that error.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

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

SUPPLEMENTARY INFORMATION:

In FR Doc. 00-15864, appearing on page 39098 in the **Federal Register** of June 23, 2000, the following correction is made:

§ 868.5115 [Corrected]

NCR1

On page 39099, in the third column, in § 868.5115 *Device to relieve acute upper airway obstruction*, in paragraph (b), insert at the end of the paragraph the sentence "The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to § 868.9."

Dated: 7/17/00
July 17, 2000

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