

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. 00N-1457]

Medical Devices; Apnea Monitor; Special Controls

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

DMB

Display Date	9-21-00
Publication Date	9-22-00
Certified	<i>S. Reese</i>

SUMMARY: The Food and Drug Administration (FDA) is publishing a proposed rule to create a separate classification for the apnea monitor. The device currently is included in the generic type of device called breathing frequency monitors. The apnea monitor will remain in class II, but will be subject to a special control. The special control is an FDA guidance document that identifies minimum performance, testing, and labeling recommendations for the device. Elsewhere in this issue of the **Federal Register**, FDA is withdrawing a proposed mandatory standard for infant apnea monitors and is announcing the availability of a draft guidance document that will serve as the special control. FDA is taking these actions because it believes that they are necessary to provide reasonable assurance of the safety and effectiveness of the apnea monitor.

DATES: Submit written comments by [*insert date 90 days after date of publication in the Federal Register*].

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joanna H. Weitershausen, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8609, ext. 164.

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SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of September 10, 1982 (47 FR 39816), FDA classified devices intended to measure or monitor a patient's respiratory rate into class II (performance standards) as part of the generic group of devices known as breathing (ventilatory) frequency monitors (§ 868.2375 (21 CFR 868.2375)). Under the classification scheme set forth in section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the agency determined that performance standards were necessary to provide reasonable assurance of the safety and effectiveness of these devices.

After several initial steps, described in the notice published elsewhere in this issue of the **Federal Register** announcing the withdrawal of the proposed rule to establish a performance standard for the infant apnea monitor (withdrawal), FDA issued a proposed rule setting forth requirements for a performance standard for the infant apnea monitor (60 FR 9762, February 21, 1995). For the reasons discussed in the withdrawal, FDA determined that it is not necessary to establish a mandatory performance standard for the device.

In its place, FDA has developed a draft industry guidance document setting forth the agency's current position regarding minimum performance characteristics, test procedures and criteria, labeling, and, as appropriate, clinical testing for certain apnea monitors, i.e., the infant/child apnea monitor. The current draft guidance identifies the monitor used on this population because infants and children under 3 years old are particularly subject to the pathophysiological consequences of prolonged apneas lasting over 20 seconds in duration. The current draft guidance includes basic concepts set out in the proposed standard for the infant apnea monitor, but updates, consolidates, or eliminates certain elements of the proposed standard on the basis of comments received on the proposal and the continuing development and FDA's recognition of appropriate consensus standards.

FDA is announcing the public availability of this draft guidance document in a notice published elsewhere in this issue of the **Federal Register**. Though the draft guidance currently represents the agency's position with regard to the infant/child apnea monitor, the agency believes the performance, testing, labeling, and, as appropriate, clinical criteria in the guidance are applicable as well to the apnea monitor used on patients of other ages. In the **Federal Register** notice announcing the public availability of this draft guidance, the agency invites comment on these specific issues.

FDA intends to modify the current guidance in the next draft, including the development of minimum clinical study parameters, so that it represents the agency's current thinking with regard to the apnea monitor used on any age group. The final industry guidance document will describe the minimum performance, testing, labeling, and clinical testing criteria that the agency believes will provide, in conjunction with the general controls of the act, reasonable assurance of the safety and effectiveness of the apnea monitor.

II. Proposed Rule

In this rule, FDA is proposing to revise current § 868.2375(a) to state that the section does not apply to the apnea monitor. This proposed change is stated in the last sentence.

To identify operational parameters in conformance with technology, FDA proposes revising the second sentence of § 868.2375(a) from "when the respiratory rate is outside predetermined limits" to "when the respiratory rate, averaged over time, is outside operator settable limits." Including "averaged over time" distinguishes the differences between a breathing frequency monitor and an apnea monitor. The breathing frequency monitor averages the breath rate over a given time (i.e., 30 seconds, 1 minute) and, then, alarms at the settings the operator has made. The limits are set by the operator and, therefore, are not predetermined. In contrast, the apnea monitor alarms when the next breath is not detected in a set time.

FDA also proposes adding § 868.2377 to classify the apnea monitor in class II and designate the guidance document entitled "Guidance for Apnea Monitor 510(k) Submissions" as a special

control for the device. The apnea monitor identified in proposed § 868.2377(a) includes, but is not limited to, the infant/child apnea monitor intended for use on infants under 1 year old and children under 3 years old.

FDA will issue the final guidance document identified as the special control in proposed § 868.2377(b) upon considering comments received on the draft guidance currently entitled “Guidance for Infant/Child Apnea Monitor 510(k) Submissions.” As noted above, FDA believes the recommendations it makes in this guidance regarding apnea monitors used for infants and children are applicable as well to apnea monitors used for patients in other age groups. Thus, FDA will modify the final guidance document so that it represents the agency’s current thinking regarding the performance characteristics, test procedures and criteria, labeling recommendations, and clinical study parameters that are needed, in conjunction with general controls, to reasonably assure the safety and effectiveness of the apnea monitor.

III. 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.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive

Order. This proposal to classify the apnea monitor in class II as a type of device that is separate from the breathing frequency monitor, and subject to the special control of industry guidance issued by FDA, will not require any firm that currently is legally distributing an apnea monitor to comply with guidance recommendations issued by FDA for the devices. Subsequent to FDA issuance of the final classification rule and the final industry guidance document, a firm submitting a 510(k) premarket notification for a “new” apnea monitor will need to address guidance recommendations. However, the firm need only show that its device is as safe and effective as a device that meets guidance recommendations. The firm may use alternative approaches if those approaches meet the performance, testing, labeling, and clinical study parameters described in the guidance.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. In the past 10 years, the agency estimates that it has received, on average, approximately four 510(k) submissions per year for breathing frequency monitor devices. FDA estimates that only one or two of these submissions per year pertained to apnea monitor devices. In addition, in November 1993, the agency issued a guidance document,¹ made available to industry, which described evaluation criteria used by reviewers in FDA’s Center for Devices and Radiological Health to review 510(k) submissions for apnea monitors. Many criteria in the November 1993 document correspond to performance, testing, and labeling recommendations in the draft industry guidance for infant/child apnea monitors. The latter guidance, as noted previously, will be modified and become the special control guidance referenced in this apnea monitor classification proposal.

Based on the above, FDA believes that, on average, no more than two 510(k)’s per year will be submitted for “new” apnea monitors by firms that must address performance, testing, and labeling parameters recommended in the special control guidance document issued by the agency as final guidance after considering comments on the draft guidance. The agency believes

¹ “Reviewer Guidance for Premarket Notification Submissions November 1993, Anesthesiology and Respiratory Devices Branch, Division of Cardiovascular, Respiratory, and Neurological Devices.”

that the final guidance document constituting the special control will not set out performance, testing, or labeling criteria of a type not previously recommended for apnea monitor devices. FDA also believes that, under normal business practices in response to competitive market forces over the past 10 years, the manufacturer of an apnea monitor will have in place designs and procedures that meet any updated recommendations in FDA's final guidance document.

Because of the above factors, FDA believes apnea monitor manufacturers will incur no costs other than those associated with the submission of 510(k) premarket notifications for "new" monitors. FDA has estimated this cost to be \$6,000 per submission on the basis that it takes device firms approximately 80 hours to complete a 510(k) package (exclusive of preparing clinical data, research, etc.) and costs an average of \$75.00 per hour to perform this type of work. Thus, FDA estimates the cost to industry of this classification proposal to be approximately \$12,000 per year (\$6,000 per 510(k) submission x 2 submissions per year). Therefore, the agency certifies that this proposal, if finalized, will not have a significant economic impact on a substantial number of small businesses.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) 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 of 1995 does not require FDA to prepare a statement of costs and benefits for the proposed rule, because the proposed rule is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted for inflation.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The burden hours required for proposed § 868.2377 are reported and approved under OMB Control No. 0910-0120.

VI. Federalism

FDA has analyzed this proposed 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.

VII. Submission of Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by [*insert date 90 days after date of publication in the Federal Register*]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

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, it is proposed that 21 CFR part 868 be 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 868.2375(a) is revised to read as follows:

§ 868.2375 Breathing frequency monitor.

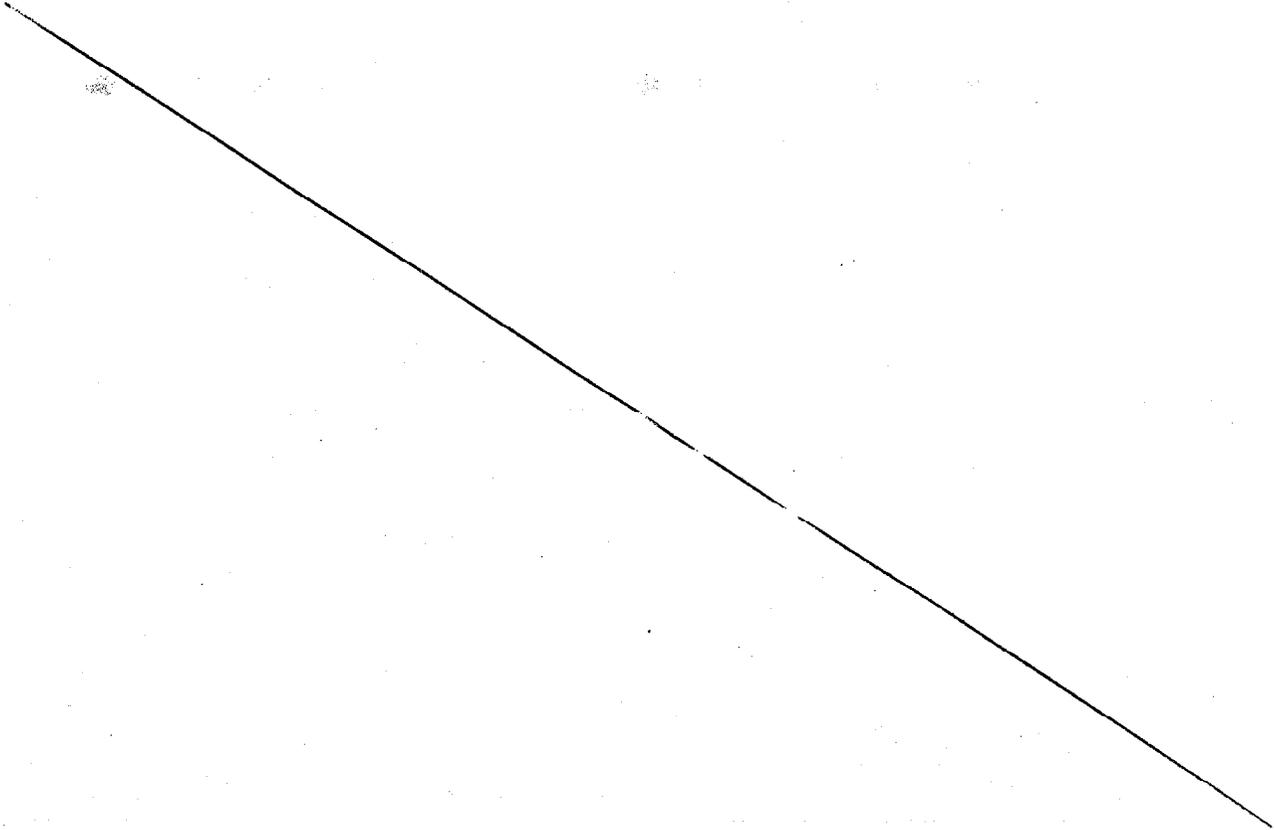
(a) *Identification.* A breathing (ventilatory) frequency monitor is a device intended to measure or monitor a patient's respiratory rate. The device may provide an audible or visible alarm when the respiratory rate, averaged over time, is outside operator settable limits. This device does not include the apnea monitor classified in § 868.2377.

* * * * *

3. Section 868.2377 is added to subpart C to read as follows:

§ 868.2377 Apnea monitor.

(a) *Identification.* An apnea monitor is a complete system intended to alarm primarily upon the cessation of breathing timed from the last detected breath. The apnea monitor includes a secondary modality, such as heart rate monitoring, that will alarm in response to the physiological consequences of apnea.



(b) *Classification*. Class II (special controls) (Guidance document: "Guidance for Apnea Monitor 510(k) Submissions").

Dated: 9/1/00
September 1, 2000.

Linda S. Kahan

Linda S. Kahan,
Deputy Director for Regulations Policy,
Center For Devices and Radiological Health.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

Sybil N. Rose