

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. 99N-0035]

JMB

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Medical Devices; Reclassification of Three Anesthesiology Preamendments Class III Devices into Class II

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying three anesthesiology preamendments devices from class III (premarket approval) into class II (special controls). FDA is also identifying the special controls that the agency believes will reasonably ensure the safety and effectiveness of the devices. This reclassification is being undertaken on the agency's own initiative based on new information under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices Act of 1990 and the FDA Modernization Act of 1997.

DATES: This rule is effective *[insert date 30 days after date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Christy Foreman, Division of Cardiovascular and Respiratory Devices (HFZ-450), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8609.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 15, 1999 (64 FR 12774), FDA published a proposed rule to reclassify 38 preamendments class III devices into class II and to establish special controls for these devices. FDA invited interested persons to comment on the proposed rule by June 14,

1999. FDA had not made the guidance documents that were proposed as special controls for the three anesthesiology devices available for comment through FDA's good guidance practices (GGPs). In the **Federal Register** of November 22, 2000, FDA announced the availability of two guidance documents for these devices (65 FR 70357) and reopened the comment period on the reclassification of the three devices (65 FR 70325) until February 20, 2001. FDA received no comments on the proposed reclassification of these three devices.

In this final rule, FDA is reclassifying the three devices into class II with a guidance document entitled "Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA" as the special control. The guidance document combines and supersedes "Guidance for Electrical Safety, Electromagnetic Compatibility and Mechanical Testing for Indwelling Blood Gas Analyzer Premarket Notification Submissions" and "Guidance for Indwelling Blood Gas Analyzer 510(k) Submissions," which in turn incorporated the special controls listed separately in the proposed rule to reclassify these devices.

The devices that are being reclassified in this final rule are:

- Indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzer (21 CFR 868.1150),
- Indwelling blood hydrogen ion concentration (pH) analyzer (21 CFR 868.1170), and
- Indwelling blood oxygen partial pressure (P_{O_2}) analyzer (21 CFR 868.1200).

II. FDA's Conclusion

FDA has concluded, based on a review of the available information, that the guidance document "Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA," in conjunction with general controls, provides reasonable assurance of the safety and effectiveness of these three devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the final guidance document.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this final rule 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 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. Reclassification of these devices from class III will relieve all manufacturers of these devices of the cost of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e). Moreover, compliance with special controls proposed for these devices will not impose significant new costs on affected manufacturers because most of these devices already comply with the proposed special controls. Because reclassification will reduce regulatory costs with respect to these devices, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this rule will not impose costs of \$100 million or more on either the private sector or State, local,

and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform 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.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 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 868.1150 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 868.1150 Indwelling blood carbon dioxide partial pressure (Pco₂) analyzer.

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(b) *Classification.* Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA.”

3. Section 868.1170 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer.

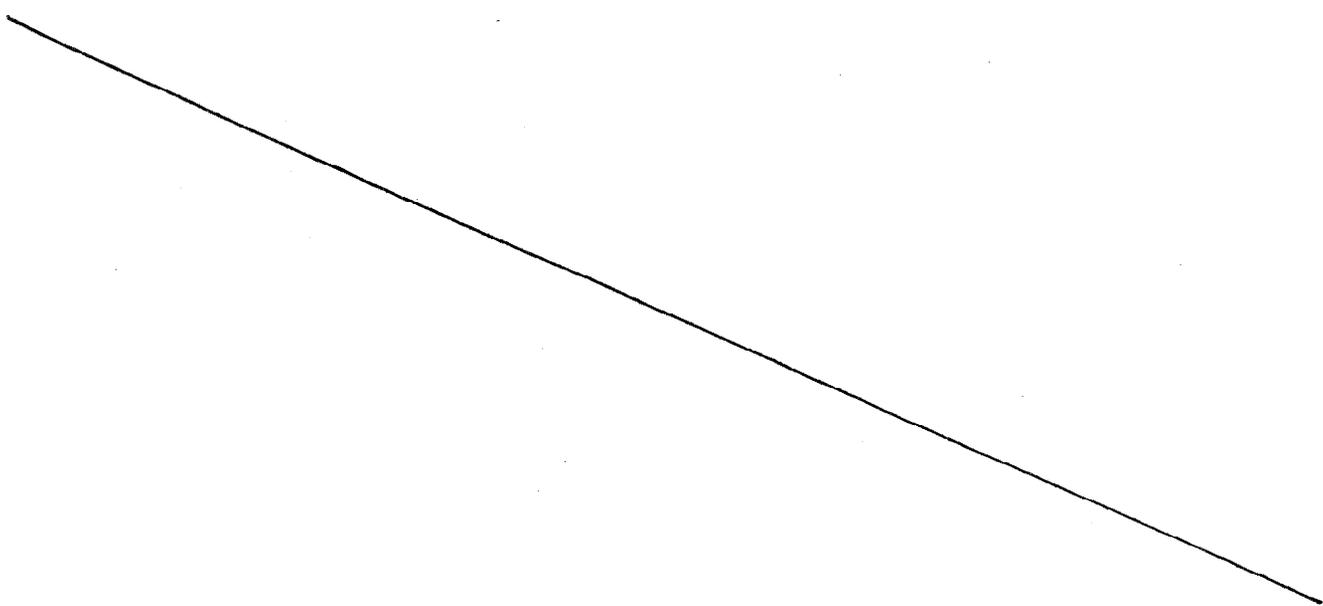
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(b) *Classification.* Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA.”

4. Section 868.1200 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 868.1200 Indwelling blood oxygen partial pressure (Po₂) analyzer.

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(b) *Classification*. Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA."

Dated: 11/4/01
November 4, 2001.

Linda A. Kahan

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