

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

DMB

Display Date	2-11-02
Publication Date	2-12-02
Certifier	R. LEDESMA

[Docket No. 01 N-05761

**Medical Devices; Reclassification of the Cutaneous Carbon Dioxide (PcCO<sub>2</sub>) and the Cutaneous Oxygen (PcO<sub>2</sub>) Monitor**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

---

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to reclassify the cutaneous carbon dioxide (PcCO<sub>2</sub>) monitor from class II (performance standards) into class II (special controls). FDA is also proposing to reclassify the cutaneous oxygen (PcO<sub>2</sub>) monitor for an infant patient who is not under gas anesthesia from class II (performance standards) into class II (special controls) and is repropounding the reclassification of the cutaneous oxygen (PcO<sub>2</sub>) monitor for all other uses from class III (premarket approval) into class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance document entitled "Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO<sub>2</sub>) and Oxygen (PcO<sub>2</sub>) Monitors; Draft Guidance for Industry and FDA" which would serve as the special control if this proposal becomes final.

These reclassifications are 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 Medical Device Amendments of 1976 (the 1976 amendments), the Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration **Modernization Act of 1997**.

**DATES:** Submit written or electronic comments on the proposed rule by *[insert date 60 days after date of publication in the **Federal Register]***. See section IV of this document for the proposed effective date of a final rule based on this document.

**ADDRESSES:** Submit written comments to the Docket Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** William A. Noe, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8609, ext. 174.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. Cutaneous Carbon Dioxide (PcCO<sub>2</sub>) Monitor*

In the **Federal Register** of July 25, 1988 (53 FR 27878), FDA issued for public comment the recommendation of the Anesthesiology and Respiratory Therapy Devices Panel that FDA reclassify the cutaneous carbon dioxide (PcCO<sub>2</sub>) monitor from class III into class II. On December 9, 1988, FDA sent to all known manufacturers of the device a letter (order) that classified the cutaneous carbon dioxide monitor, and substantially equivalent devices of this generic type, from class III to class II. In **the Federal Register** of June 28, 1989 (54 FR 27160), FDA published a final rule reclassifying the cutaneous carbon dioxide monitor from class III (premarket approval) into class II (performance standards) and added new 21 *CFR* 868.2480 *Cutaneous carbon dioxide (PcCO<sub>2</sub>) monitor*.

*B. Cutaneous Oxygen (PcO<sub>2</sub>) Monitor*

In **the Federal Register** of November 2, 1979 (44 FR 63292), FDA published a proposal to classify 149 anesthesiology devices, including the cutaneous oxygen monitor (§ 868.2500). In **the Federal Register** of July 16, 1982 (47 FR 31130), FDA published a final rule classifying

the cutaneous oxygen monitor into either class II or class III, depending on the intended use of the device. The cutaneous oxygen monitor intended for use in monitoring infant patients who are not under gas anesthesia was classified as class II (performance standards). This action was based on FDA's belief that there was sufficient data to show the device is safe and effective for this use and that a performance standard would provide reasonable assurance of safety and effectiveness of the device. The final rule also classified into class III the cutaneous oxygen monitor intended for all other uses, that is, in a noninfant patient or in any patient, including an infant, who is under gas anesthesia

In the **Federal Register** of August 14, 1995 (60 FR 41984 and 41986), FDA published two orders for certain class III devices requiring the submission of safety and effectiveness information in accordance with the preamendments class III strategy for implementing section 515(i) of the act (21 U.S.C. 360e(i)), and providing deadlines for submission of the information. In response to that notice, on October 21, 1996, Radiometer Medical A/S submitted a request for reclassification of the cutaneous oxygen monitor for use in noninfant patients not under gas anesthesia.

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. Among the 38 preamendments devices was the cutaneous oxygen monitor intended for all uses other than in an infant patient who is not under gas anesthesia. An American Society for Testing and Materials standard was proposed as the special control. FDA invited interested persons to comment on the proposed rule by June 14, 1999. FDA received six comments and two requests for extension of the comment period for certain devices. One of the requests for extension of the comment period was from a manufacturer of the cutaneous oxygen monitor. The manufacturer recently withdrew this request. None of the comments addressed the cutaneous oxygen monitor.

In the **Federal Register** of March 31, 2000 (63 FR 17138), FDA published a final rule reclassifying 28 of the 38 devices for which it had proposed reclassification. FDA reopened the

comment period for 6 of the 38 devices (Vascular graft prosthesis of less than 6 millimeters diameter, 21 CFR 870.3450; Pacemaker lead adapter, 21 CFR 870.3620; Annuloplasty ring, 21 CFR 870.3800; Cardiopulmonary bypass defoamer, 21 CFR 870.4230; Cardiopulmonary bypass arterial blood line filter, 21 CFR 870.4260; and Cardiopulmonary bypass oxygenator, 21 CFR 870.4350) for which it had proposed reclassification and intends to reopen the comment period for 3 other devices in the near future. The remaining of the 38 preamendments devices is the cutaneous oxygen monitor. FDA is, in this notice, reproposing the reclassification of the cutaneous oxygen monitor for all other uses from class III (premarket approval) into class II (special controls).

## **II. Proposed Rule**

FDA is proposing to reclassify the cutaneous carbon dioxide ( $\text{PcCO}_2$ ) monitor and the cutaneous oxygen ( $\text{PcO}_2$ ) monitor intended for use in monitoring infant patients who are not under gas anesthesia, from class II (performance standards) into class II (special controls).

Under the 1976 amendments, class II devices were defined as those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish performance standards to provide such assurance. SMDA broadened the definition of class II devices to mean those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, -recommendations, and any other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act (21 U.S.C. 360c(a)(1)(B))). At the time the cutaneous carbon dioxide ( $\text{PcCO}_2$ ) monitor and the cutaneous oxygen ( $\text{PcO}_2$ ) monitor intended for use in monitoring infant patients who are not under gas anesthesia were classified, 1987 and 1982 respectively, special controls were not a regulatory option. FDA has now developed a draft guidance and is proposing to make it the special control for these products.

FDA is also reproposing the reclassification of the cutaneous oxygen monitor for all other uses from class III (premarket approval) into class II (special controls). In the original March 15, 1999, proposal, FDA had announced its tentative determination that classification into class II with four consensus standards as the special controls would provide reasonable assurance of the safety and effectiveness of the cutaneous oxygen monitor. The agency received no comments on the proposed reclassification of the cutaneous oxygen monitor. Under the SMDA authority, FDA is now proposing a guidance document as the special controls.

FDA is identifying the guidance document entitled “Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ( $PcCO_2$ ) and Oxygen ( $PcO_2$ ) Monitors; Draft Guidance for Industry and FDA” that would serve as the special control for the cutaneous oxygen ( $PcO_2$ ) monitor for both intended uses and for the cutaneous carbon dioxide ( $PcCO_2$ ) monitor, if this proposal becomes final.

The draft guidance document sets forth the information FDA believes should be included in a 510(k) for these devices. FDA has identified the following as the risks to health presented by these devices (first column of the table below). The second column identifies the portions of the guidance document that address these risks to health. FDA believes that addressing these risks to health in a 510(k) in the manner identified in the guidance document, or an acceptable alternative, is necessary to provide reasonable assurance of the safety and effectiveness of these devices.

TABLE 1.

Identified Risk	Recommended Mitigation Measures
Electrical Shock Electromagnetic Interference Toxicity Tissue Reactivity Burns Inaccurate Measurement	Electrical Safety Standards Electromagnetic Compatibility Standards Biocompatibility and Sterility Guidance Biocompatibility and Sterility Guidance Performance Testing Requirements

### III. Special Controls

The proposed special control for these devices is FDA’s “Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ( $PcCO_2$ ) and Oxygen ( $PcO_2$ ) Monitors; Draft Guidance for Industry and FDA.” FDA is announcing the public availability of the draft guidance in a notice

published elsewhere in this issue of the **Federal Register** and invites interested persons to comment.

#### **IV. Proposed Dates**

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

#### **V. Environmental Impact**

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

#### **VI. 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. 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. 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 rule will not have a significant economic impact on a substantial number of small entities. In addition, this proposed 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.

### **VII. Paperwork Reduction Act of 1995**

FDA concludes that this proposed 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.

### **VIII. Comments**

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this proposed rule by *[insert date 60 days after date of publication in the **Federal Register**]*. Submit two copies of any comments, except individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The proposed rule and 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 868.2480 is amended by revising paragraph (b) to read as follows:

**§ 868.2480 Cutaneous carbon dioxide (PcCO<sub>2</sub>) monitor.**

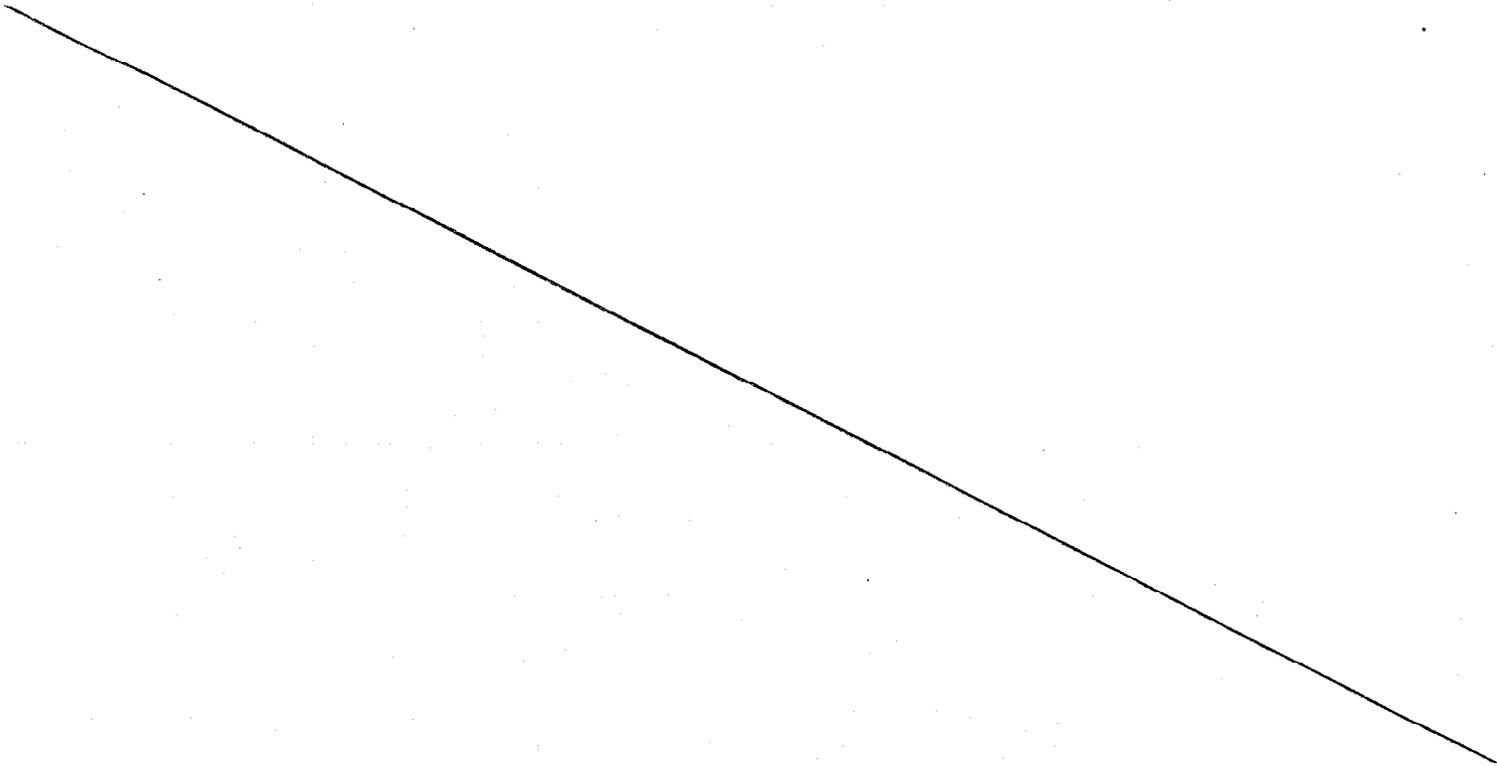
\* \* \* \* \*

(b) *Classification.* Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO<sub>2</sub>) and Oxygen (PcO<sub>2</sub>) Monitors; Final Guidance for Industry and FDA.”

3. Section 868.2500 is revised to read as follows:

**§ 868.2500 Cutaneous oxygen (PcO<sub>2</sub>) monitor.**

(a) *Identification.* A cutaneous oxygen (PcO<sub>2</sub>) monitor is a noninvasive, heated sensor (e.g., a Clark-type polarographic electrode) placed on the patient’s skin that is intended to monitor relative changes in the cutaneous oxygen tension.



(b) *Classification*. Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO<sub>2</sub>) and Oxygen (PcO<sub>2</sub>) Monitors; Guidance for Industry and FDA."

Dated: 1/29/02  
January 29, 2002.

Linda S. Kahan

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

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

**BILLING CODE 4160-01-S**

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

Regin Ledesma