PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. FAA amends § 39.13 by adding a new AD to read as follows:

2001–01–07 Reims Aviation S.A.: Amendment 39–12504; Docket No. 99–CE–28–AD.

(a) *What airplanes are affected by this AD?* This AD affects Model F406 airplanes, serial numbers F406–0001 through F406–0083, certificated in any category.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to detect and correct cracks in the canted rib upper cap in the center wing carry-through area, which could result in structural failure of the wing with possible loss of control of the airplane.

(d) *What actions must I accomplish to address this problem?* To address this problem, unless already done, you must accomplish the following:

Actions	Compliance	Procedures
(1) Inspect the canted rib upper cap in the center wing carry-through area for cracks.	Within the next 75 hours time-in-service (TIS) after January 7, 2002 (the effective date of this AD), and thereafter at 200-hour TIS intervals, but not to exceed three 200-hour interval inspections (675 hours TIS: 75-hour TIS initial inspection plus three additional 200-hour TIS repetitive inspections).	Following the ACCOMPLISHMENT INSTRUCTIONS section of REIMS/CESSNA Service Bulletin CAB98–16, dated November 2, 1998.
(2) If, during any inspection required by this AD, cracks are found, accomplish the following:.	Before further flight after the inspection where the crack is found.	Following the ACCOMPLISHMENT INSTRUCTIONS section of REIMS-CESSNA Service Bulletin CAB98–16, dated November 2, 1998.
(i) If the cracks are less than 2 inches in length, modify the canted rib upper cap in the center wing carry-through area.		
(ii) If the cracks are 2 inches in length or more, obtain a repair scheme from the manufacturer through FAA at the address specified in paragraph (f) of this AD and incorporate this repair scheme.		
(3) Modify the canted rib upper cap in the center wing carry-through area.	Within 600 hours TIS after the initial inspection required by paragraph (d)(1) of this AD, unless already accomplished through paragraphs (d)(2)(i) or (d)(2)(ii) of this AD.	Following the ACCOMPLISHMENT INSTRUCTIONS section of REIMS-CESSNA Service Bulletin CAB98–16, dated November 2, 1998.
(4) Accomplishing the repair or modification required in paragraphs (d)(2)(i), (d)(2)(ii), or (d)(3) of this AD is considered terminating action for the inspection requirements of this AD.	Not applicable	Not applicable.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 1: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner-operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Brian A. Hancock, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4143, facsimile: (816) 329–4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with REIMS/CESSNA Service Bulletin CAB98–16, dated November 2, 1998. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You can get copies from Cessna Aircraft Company, Product Support, PO Box 7706, Wichita, Kansas 67277. You can look at copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(i) *When does this amendment become effective?* This amendment becomes effective on January 7, 2002.

Note 2: The subject of this AD is addressed in French AD 1999–087(A), dated February 24, 1999.

Issued in Kansas City, Missouri, on November 6, 2001.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–28571 Filed 11–14–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. 99N–0035]

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 December 17, 2001.

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 (Pco_2) analyzer (21 CFR 868.1150),
- Indwelling blood hydrogen ion concentration (pH) analyzer (21 CFR 868.1170), and
- Indwelling blood oxygen partial pressure (Po_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 (Pco_2) analyzer.

* * * * *

(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.

* * * * *

(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 (Po_2) analyzer.

* * * * *

(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: November 4, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 01–28561 Filed 11–14–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. 01N–0238]

Medical Devices; Exemptions From Premarket Notification; Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing a final rule exempting from the premarket notification requirements the fluoroscopic compression device, a manual compression device that allows a radiologist to press on the abdomen during a fluoroscopic procedure without exposing his or her hand to the x-ray beam. The device is classified as an accessory to the image-intensified fluoroscopic x-ray system. FDA received a petition requesting an exemption for the F-Spoon device, a type of fluoroscopic manual compression device. FDA is expanding the exemption for this type of generic device to include other fluoroscopic compression devices. FDA is publishing this order in accordance with the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: This rule is effective December 17, 2001.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Public Law 94–295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Public Law 101–629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use that is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976, (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations (21 CFR part 807) require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that 1 day after date of publication of the list under section 510(m)(1) of the act, FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance that the agency issued on February 19, 1998, entitled ''Procedures for Class II