Issued in Kansas City, MO on March 30, 2000.

Herman J. Lyons, Jr.

Manager, Air Traffic Division, Central Region.

[FR Doc. 00–8966 Filed 4–10–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99–ACE–56]

Amendment to Class E Airspace; Grand Island, NE

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of a direct final rule which revises Class E airspace at Grand Island, NE.

DATES: The direct final rule published at 65 FR 5765 is effective on 0901 UTC, June 15, 2000.

FOR FURTHER INFORMATION CONTACT: Brenda Mumper, Air Traffic Division, Airspace Branch, ACE–520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2524.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on February 7, 2000 (65 FR 5765). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on June 15, 2000. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO on March 30, 2000.

Herman J. Lyons, Jr.,

Manager, Air Traffic Division, Central Region.

[FR Doc. 00–8967 Filed 4–10–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 870, 888, and 890

[Docket No. 99N–2210]

Cardiovascular, Orthopedic, and Physical Medicine Diagnostic Devices; Reclassification of Cardiopulmonary Bypass Accessory Equipment, Goniometer Device, and Electrode Cable Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying from class I into class II the cardiopulmonary bypass accessory equipment device that involves an electrical connection to the patient, the goniometer device, and the electrode cable. FDA is also exempting these devices from the premarket notification requirements. FDA is reclassifying these devices on its own initiative based on new information. FDA is taking this action to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices.

DATES: This regulation is effective May 11, 2000.

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. Background (Proposed Rule)

On August 9, 1999 (64 FR 43114), FDA, on its own initiative, proposed to reclassify the following devices from class I to class II: (1) Cardiopulmonary bypass accessory equipment, when intended to be used in the cardiopulmonary bypass circuit to support, adjoin, or connect components, or to aid in the setup of the extracorporeal line; (2) the goniometer device, which is an AC-powered device, when intended to evaluate joint function by measuring and recording ranges of motion, acceleration, or forces exerted by a joint; and (3) the electrode cable device, which is an electrode cable device composed of strands of insulated electrical conductors laid together around a central core and intended for medical purposes to connect an electrode from a patient to a diagnostic machine.

In addition to general controls, FDA identified two special controls that FDA believes are adequate to control the risks to health described for these devices: (1) On May 9, 1997, FDA issued a final rule establishing a performance standard for electrode lead wires and patient cables. The agency determined that the performance standard is needed to prevent electrical connections between patients and electrical power sources. In the preamble to the May 9, 1997, final rule establishing this standard, FDA identified cardiopulmonary bypass accessory equipment, the goniometer, and the electrode cable as devices that would be subject to this standard after they were reclassified into class II; and (2) based on the available information, FDA also identified a guidance document entitled ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables.'' The guidance provides information on electrocution hazards posed by unprotected patient electrical connectors. The guidance is intended to help affected parties understand the steps needed to achieve compliance with the performance standard for electrode lead wires and patient cables.

Since May 11, 1998, electrode lead wires or patient cables have been required to comply with the ECG Cables and Lead Wires, ANSI/AAMI EC 53–1995 standard if they are intended for use with any of the following devices:

1. Breathing frequency monitors,
2. Ventilatory effort monitors (Apnea detectors),
3. Electrocardiographs (ECG's),
4. Radio frequency physiological signal transmitters and receivers,
5. Cardiac monitors,
6. Electrocardiograph electrodes (including pre-wired ECG electrodes),
7. Patient transducer and electrode cables (including connectors),
8. Medical magnetic tape recorders (e.g. Holter monitors),
9. Arrhythmia detectors and alarms,
10. Telephone electrocardiograph transmitters and receivers.

Manufacturers and users had an additional 2 years to prepare for the second phase of implementation of the standard. Beginning on May 9, 2000, any electrode lead wire or patient cable lead intended for use with any medical device must comply with the standard. The performance standard incorporates the specific requirements of international standard, IEC–60601, clause 56.3(c), which requires leads to be constructed in such a manner as to preclude patient contact with hazardous voltages or, for certain devices, contact with electrical ground. Design changes and labeling changes need to be

considered by manufacturers and importers of these devices. Adapters can be used to convert devices already in the marketplace so they can accept electrode wires and patient cables that comply with the new performance standard.

II. Comments

FDA invited interested persons to submit written comments on the proposed rule. FDA received one comment. The comment objected that the rule should not apply to battery-powered goniometers.

FDA agrees in part. Some battery-powered goniometers have cables and leads that connect them to displays and other devices. Because devices that use electrode lead wires and patient cables present the risk of electrocution to the patient, FDA believes that these devices should be in class II and subject to the standard. Goniometers that do not use electrode lead wires and patient cables will remain in class I and will be exempt from premarket notification. FDA is also revising the identification section in § 888.1500 (21 CFR 888.1500). Presently, it refers only to AC-powered devices. Since publication of that proposed rule, FDA has found several battery-powered goniometers to be substantially equivalent to the goniometer identified in § 888.1500(a). FDA is revising this section to include battery-powered devices.

III. Exemption From Premarket Notification

A. FDA Is Exempting These Devices From Premarket Notification

On November 21, 1997, the President signed into law the FDA Modernization Act (FDAMA) (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(m). 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 the 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. FDA has determined that, for the devices proposed for class II in this rule, the special controls along with general controls other than premarket notification will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is exempting these devices from the premarket notification requirements subject to the applicable limitations on exemptions.

B. Certain Cardiopulmonary Bypass Equipment Will Remain in Class I

FDAMA also added a new section 510(l) to the act which provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. FDA refers to the devices that meet these criteria as ''reserved.'' In the **Federal Register** of February 2, 1998 (63 FR 5387), FDA published a list of devices it considered reserved and that require premarket notification and a list of devices it believed met the exemption criteria in FDAMA. FDA invited comments on the February 2, 1998, notice. In the **Federal Register** of November 12, 1998 (63 FR 63222), after reviewing the comments submitted on the February 2, 1998, **Federal Register** notice, FDA proposed to designate which devices require premarket notification, and which are exempt, subject to limitations, under notice and comment rulemaking proceedings under new section 510(l) of the act. One comment on the proposed rule stated that, for cardiopulmonary bypass accessory equipment, the ''reserved'' designation should be limited to accessory equipment that involves an electrical connection to the patient. FDA agrees with this comment and, on January 14, 2000 (65 FR 2296), FDA issued a final rule on exemptions from premarket notification to adopt this comment. In this rule, FDA stated that cardiopulmonary bypass accessory equipment that does not involve electrical connection to the patient is a class I device and is exempt from the premarket notification requirements.

IV. 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.

V. 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 rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the 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. Based on the May 9, 1997 (62 FR 25477), **Federal Register**, a final rule was issued establishing a performance standard for electrode lead wires and patient cables, which included and applied to the cardiopulmonary bypass accessory equipment that involves an electrical connection to the patient, the goniometer, and the electrode cable. FDA's analysis determined that the imposition of the performance standard would not have a significant economic impact on a substantial number of small entities. This reclassification will have no economic effect other than the imposition of this standard. In addition, the 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 or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VI. Paperwork Reduction Act of 1995

FDA has determined that this rule contains no collections of information. Therefore, clearance from the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Parts 870, 888, and 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 870, 888, and 890 are amended as follows:

PART 870—CARDIOVASCULAR DEVICES

1. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 870.4200 is revised to read as follows:

§ 870.4200 Cardiopulmonary bypass accessory equipment.

(a) *Identification.* Cardiopulmonary bypass accessory equipment is a device that has no contact with blood and that is used in the cardiopulmonary bypass circuit to support, adjoin, or connect components, or to aid in the setup of the extracorporeal line, e.g., an oxygenator mounting bracket or system-priming equipment.

(b) *Classification.* (1) Class I. The device is classified as class I if it does not involve an electrical connection to the patient. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 870.9.

(2) Class II (special controls). The device is classified as class II if it involves an electrical connection to the patient. The special controls are as follows:

(i) The performance standard under part 898 of this chapter, and

(ii) The guidance document entitled ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables.'' The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 870.9.

PART 888—ORTHOPEDIC DEVICES

3. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

4. Section 888.1500 is revised to read as follows:

§ 888.1500 Goniometer.

(a) *Identification.* A goniometer is an AC-powered or battery powered device intended to evaluate joint function by measuring and recording ranges of motion, acceleration, or forces exerted by a joint.

(b) *Classification.* (1) Class I (general controls) for a goniometer that does not use electrode lead wires and patient cables. This device is exempt from the premarket notification procedures of subpart E of part 807 of this chapter subject to § 888.9.

(2) Class II (special controls) for a goniometer that uses electrode lead wires and patient cables. The special controls consist of:

(i) The performance standard under part 898 of this chapter, and

(ii) The guidance entitled ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables.'' This device is exempt from the premarket notification procedures of subpart E of part 807 of this chapter subject to § 888.9.

PART 890—PHYSICAL MEDICINE DEVICES

5. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

6. Section 890.1175 is amended by revising paragraph (b) to read as follows:

§ 890.1175 Electrode cable.

* * * * *

(b) *Classification.* Class II (special controls). The special controls consist of:

(1) The performance standard under part 898 of this chapter, and

(2) The guidance document entitled ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables.'' This device is exempt from the premarket notification procedures of subpart E of part 807 of this chapter subject to § 890.9.

Dated: March 2, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–8850 Filed 4–10–00; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IN107–1a; FRL–6573–8]

Approval and Promulgation of Implementation Plan; Indiana Particulate Matter Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: On February 3, 1999, the State of Indiana Department of Environmental Management (IDEM) submitted a site-specific State Implementation Plan (SIP) request to revise Particulate Matter (PM) emission limits for a facility owned by Central Soya Company, Inc., located in Indianapolis, Marion County, Indiana. Central Soya is converting its grain elevator from a processing to a storage facility. The SIP revision request reflects changes in emission limits resulting from the shutdown of various operations at the plant, and provides new emission limits reflecting the addition of new operations.

The projected PM emission decrease associated with the elimination of selected activities at the facility is 71.22 tons per year. The projected PM emission increases associated with the changes in operations at the facility is 14.81 tons per year. The overall change is a projected net decrease in PM emissions of approximately 56 tons per year from the facility. Because Indiana's Central Soya SIP revision request is consistent with the Clean Air Act and applicable policy, EPA is approving it.

DATES: This rule is effective on June 12, 2000, unless EPA receives adverse written comments by May 11, 2000. If adverse comment is received, EPA will publish a timely withdrawal of the rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments should be sent to: J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. You can inspect copies of the State Plan submittal at the following address: U.S. Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (We recommended that you contact Mark J. Palermo at (312) 886–6082 before visiting the Region 5 Office.)

FOR FURTHER INFORMATION CONTACT: John Paskevicz, Environmental Engineer, at (312) 886–6084.

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us'' or ''our'' are used, we mean EPA. Also, whenever we refer to ''Central Soya'', we mean Central Soya Company, Incorporated, at 1102 West 18th Street in Marion County, Indianapolis, Indiana.

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