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

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Manager, Air Traffic Division, Central Region.

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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.

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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