

final rule is not a significant regulatory action as defined by the Executive Order and so it 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 to class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs. The agency, therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final 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 is not required.

IV. Paperwork Reduction Act of 1995

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.

V. Reference

The following reference has been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from 3CPM Co., Inc., dated July 12, 1999.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

List of Subjects in 21 CFR Part 876

Medical devices.

PART 876—GASTROENTEROLOGY—UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

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

2. Section 876.1735 is added to subpart B to read as follows:

§ 876.1735 Electrogastrography system.

(a) *Identification.* An electrogastrography system (EGG) is a device used to measure gastric

myoelectrical activity as an aid in the diagnosis of gastric motility disorders. The device system includes the external recorder, amplifier, skin electrodes, strip chart, cables, analytical software, and other accessories.

(b) *Classification.* Class II (Special Controls). The special controls are as follows:

(1) The sale, distribution and use of this device are restricted to prescription use in accordance with § 801.109 of this chapter.

(2) The labeling must include specific instructions:

(i) To describe proper patient set-up prior to the start of the test, including the proper placement of electrodes;

(ii) To describe how background data should be gathered and used to eliminate artifact in the data signal;

(iii) To describe the test protocol (including the measurement of baseline data) that may be followed to obtain the EGG signal; and

(iv) To explain how data results may be interpreted.

(3) The device design should ensure that the EGG signal is distinguishable from background noise that may interfere with the true gastric myoelectric signal.

(4) Data should be collected to demonstrate that the device has adequate precision and the EGG signal is reproducible and is interpretable.

Dated: September 16, 1999.

Linda S. Kahan,

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

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01-99-162]

Drawbridge Operation Regulations: Hackensack River, NJ

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations governing the operation of the Portal Bridge, mile 5.0, across the Hackensack River in Little Snake Hill, New Jersey. This deviation allows the bridge owner to keep the bridge in the closed position from 9 p.m. on September 24, 1999, to 9 a.m. on

September 25, 1999, and from 9 p.m. on September 25, 1999, to 9 a.m. on September 26, 1999. This deviation is necessary to facilitate the rehabilitation of the signal and switch system at the bridge.

DATES: This deviation is effective from September 24, 1999, to September 26, 1999.

FOR FURTHER INFORMATION CONTACT: Ms. Judy Yee, Project Officer, First Coast Guard District, at (212) 668-7165.

SUPPLEMENTARY INFORMATION: The Portal Bridge, mile 5.0, across the Hackensack River has vertical clearances of 23 feet at mean high water, and 28 feet at mean low water in the closed position. The current operating regulations listed at 33 CFR 117.723(c) require the bridge to open on signal; except that, from Monday through Friday, except federal holidays, the draw need not open from 7:20 a.m. to 9:20 a.m. and from 4:30 p.m. to 6:50 p.m. At all other times, an opening may not be delayed for more than ten minutes, unless the drawtender and the vessel operator agree to a longer delay.

The bridge owner, AMTRAK, requested a temporary deviation from the operating regulations for the Portal Bridge in order to rehabilitate the signal and switch system at the bridge. This work will require the Portal Bridge to remain in the closed position from 9 p.m. on September 24, 1999, to 9 a.m. on September 25, 1999, and from 9 p.m. on September 25, 1999, to 9 a.m. on September 26, 1999. Vessels that can pass under the bridge without an opening may do so at all times during the closed periods. This work is essential for public safety and the continued operation of the bridge.

Thirty days notice to the Coast Guard for approval of this maintenance repair was not given by the bridge owner and was not required because this work involves vital, unscheduled maintenance that must be performed without undue delay.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to normal operation as soon as possible. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: September 14, 1999.

Robert F. Duncan,

Captain, U.S. Coast Guard, Acting Commander, First Coast Guard District.

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