Rock Hill

ROCK HILL/YORK COUNTY/BRYANT FIELD
South Carolina
NDB RWY 2, ORIG–C...
FDC Date: 09/02/99

FDC 9/6695 /UZA/ FI/P ROCK HILL/YORK COUNTY/BRYANT FIELD, ROCK HILL, SC. NDB RWY 2, ORIG–C...S–2HAA513 ALL CATS. VIS CAT C1. CIRCLING CAT C MDA 1200/HAA533. TDZE... 667; RWY 2 THLD ELEV... 677. MIN ALTITUDE AT RALLY LOM 2500. PT MIN ALT 2500. MISSED APPROACH... CLIMB TO 1500 THEN CLIMBING LEFT TURN TO 2500 DIRECT UZLOM AND HOLD. TERMINAL ROUTE FROM FML VORTAC TO RALLY LOM MIN ALT 2500. TERMINAL ROUTE FROM RICHE INT TO RALLY LOM MIN ALT 2500. DELETE NOTE... 'INOPERATIVE TABLE DOES NOT APPLY TO CAT C'. ADD... FROM UZ LOM TO RWY02 3.08 DEGREES, TCH 35. THIS IS NDB RWY 2, ORIG–D.

Rock Hill

ROCK HILL/YORK COUNTY/BRYANT FIELD
South Carolina
GPS RWY 20, ORIG–B...
FDC Date: 09/02/99

FDC 9/6696 /UZA/ FI/P ROCK HILL/YORK COUNTY/BRYANT FIELD, ROCK HILL, SC. GPS RWY 20, ORIG–B...S–20 HAT 438 ALL CATS. TDZE... 662; RWY 20 THLD ELEV... 661. CIRCLING CAT C MDA 1200/HAA 533. ADD... FROM TIPDY WP TO RY20 3.01 DEGREES, TCH 39. THIS IS GPS RWY 20, ORIG–C.

Jackson

MCKELLER-SIPES REGIONAL
Tennessee
GPS RWY 20 ORIG...
FDC Date: 09/09/99

FDC 9/6873 /MKL/ FI/P MCKELLER-SIPES REGIONAL, JACKSON, TN. GPS RWY 20 ORIG...S–20 CAT D VIS 1–1/4. THIS IS GPS RWY 20 ORIG–A.

Newport News

NEWPORT NEWS/WILLIAMSBURG INTL
Virginia
NBD OR GPS RWY 20, AMDT 3C...
FDC Date: 09/02/99
THIS REPLACES NOTAM 9/6472

FDC 9/6708/PHF/FI/P NEWPORT NEWS/WILLIAMSBURG INTL, NEWPORT NEWS, VA. NDB OR GPS RWY 20, AMDT 3C...DISTANCE FAF TO THLD... 3.31NM. ADD... FROM FLAWS INT TO RW20 2.89 DEGREES, TCH 42. THIS IS NDB OR GPS RWY 20, AMDT 3D.

Newport News

NEWPORT/NEWS/WILLIAMSBURG INTL
Virginia
NDB OR GPS RWY 2 AMDT 4A...
FDC Date: 09/09/99

FDC 9/6946/PHF/FI/P NEWPORT NEWS/WILLIAMSBURG INTL, NEWPORT NEWS, VA. NDB OR GPS RWY 2 AMDT 4A...S–2... MDA 660/HAT 620 ALL CATS. CIRCLING... MDA 660/HAA 617 ALL CATS. VIS CAT C 1 ¾. MSA FROM HENRY (PJS) NDB 090 TO 270 2300, 270 TO 090 1800. THIS IS NDB OR GPS RWY 2 AMDT 4B.

Orange

ORANGE COUNTY
Virginia
NDB RWY 7 AMDT 1...
FDC Date: 09/10/99

FDC 9/7057/OMH/FI/P ORANGE COUNTY, ORANGE, VA. NDB RWY 7 AMDT 1...TERMINAL ROUTE...PT L SIDE OF CRS 265.00 OUTBOUND 3000 FT WITHIN 10 MILES OF COG NDB. CHART BEARING FROM COG NDB TO RWY 7, 079 DEGREES, THIS IS NDB RWY 7 AMDT 1A.

Martinsburg

EASTERN WEST VIRGINIA REGIONAL/SHEPHERD FIELD
West Virginia
LOC/DME BC RWY 8 AMDT 5A...
FDC Date: 09/07/99
THIS REPLACES FDC 9/6639

FDC 9/6761/MRB/FI/P EASTERN WEST VIRGINIA REGIONAL/SHEPHERD FIELD, MARTINSBURG, WV. LOC/DME BC RWY 8 AMDT 5A...ADD... FROM GERRA/MRB 12.50 DME TO RWY 82.99 DEGREES TCH 45. PROFILE/PLAN VIEW... CHANGE NAME BITTO BCM TO BIITO BCM. THIS IS LOC/DME BC RWY 8 AMDT 5B.

Big Piney

PINEY-MARBLETON
Wyoming
VOR RWY 31 AMDT 3...
FDC Date: 08/31/99

FDC 9/6615/BPI/FI/P PINEY-MARBLETON, BIG PINEY, WY. VOR RWY 31 ADMT 3...DELETE NOTE... OBTAIN LOCAL ALSTG ON UNICOM. PROC NA WHEN BIG PINEY WYOMING ALSTG NOT AVBL. THIS IS VOR RWY 31 AMDT 3A.

Big Piney

BIG PINEY-MARBLETON
Wyoming
GPS RWY 31, ORIG...
FDC Date: 08/31/99

FDC 9/6616 /BPI/FI/P BIG PINEY-MARBLETON, BIG PINEY, WY. GPS RWY 31, ORIG...DELETE NOTE... OBTAIN LOCAL ALSTG ON CTAF. WHEN NOT RECEIVED PROC NA. ADD... FROM HICDE WP TO RWY 31 2.69 DEGREES TCH 30. CHART NOTE... VGSI AND DESCENT ANGLES NOT COINCIDENT. THIS IS GPS RWY 31 ORIG–A.

Casper

NATRONA COUNTY INTL
Wyoming
VOR/DME OR TACAN OR GPS RWY 21 ADMT 7...
FDC Date: 09/09/99

FDC 9/6875/CPR/FI/P NATRONA COUNTY INTL, CASPER, WY. VOR/DME OR TACAN OR GPS RWY 21 AMDT 7...ADD... FROM ANNVA TO RW21 3.55 DEGREES TCH 55, CHART PROFILE NOTE...VGSI AND SESCENT ANGLES NOT COINCIDENT. THIS IS VOR/DME OR TACAN OR GPS RWY 21 AMDT 7A.

Pinedale

RALPH WENZ FIELD
Wyoming
NDB OR GPS RWY 29 ORIG...
FDC Date: 09/10/99

FDC 9/7009/PNA/FI/P RALPH WENZ FIELD, PINEDALE, WY. NDB OR GPS RWY 29 ORIG...DELETE NOTE... OBTAIN LOCAL ALTIMETER ON CTAF; WHEN NOT AVAILABLE PROCEDURE NOT AUTHORIZED. THIS IS NDB OR GPS RWY 29 ORIG–A.

[FR Doc. 99–24794 Filed 9–22–99; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 99N–4027]

Medical Devices; Gastroenterology and Urology Devices; Classification of the Electrogastrography System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the electrogastrography system (EGG) into class II (special controls). The special controls that will apply to the EGG system are restriction to prescription use, certain labeling requirements, design requirements, and data collection requirements. The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as

amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997. The agency is classifying the EGG system into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This rule becomes effective October 25, 1999. The reclassification was effective August 20, 1999.

FOR FURTHER INFORMATION CONTACT: Carolyn Y. Neuland, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1220

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification.

In accordance with section 513(f)(1) of the act, FDA issued an order on July 2, 1999, classifying the 3CPM EGG Machine in class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On July 12, 1999, the 3CPM Co., Inc., submitted a petition requesting classification of the 3CPM EGG Machine under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

In accordance with 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II 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 reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition and the medical literature, FDA determined that the EGG system can be classified in class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name ''electrogastrography system,'' and it is identified as 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.

FDA has identified the following risks to health associated specifically with this type of device: (1) Misdiagnosis due to erroneous data output and (2) misuse of the device and misinterpretation of the system results by an untrained individual.

FDA believes that the special controls described below address these risks and provide reasonable assurance of the safety and effectiveness of the device. Therefore, on August 20, 1999, FDA issued an order to the petitioner classifying the device as described previously into class II subject to the special controls described below. Additionally, FDA is codifying the classification of this device by adding § 876.1735.

In addition to the general controls of the act, the 3CPM EGG Machine is subject to the following special controls: (1) The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109. (2) The labeling must include specific instructions: (a) To describe proper patient set-up prior to the start of the test, including the proper placement of electrodes; (b) to describe how background data should be gathered and used to eliminate artifact in the data signal; (c) to describe the test protocol (including the measurement of baseline data) that may be followed to obtain the EGG signal; and (d) 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.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of this type of device and, therefore, the type of device is not exempt from premarket notification requirements. Thus, persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the EGG system they intend to market.

II. 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.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), 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 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.

[FR Doc. 99–24791 Filed 9–22–99; 8:45 am]

BILLING CODE 4160–01–F

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.

[FR Doc. 99–24800 Filed 9–22–99; 8:45 am]

BILLING CODE 4910–15–M