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**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 (*insert date 30 days after date of publication in the Federal Register*). 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;

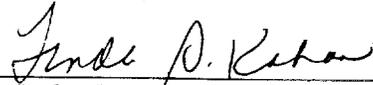
(iii) To describe the test protocol (including the measurement of baseline data) that may be followed to obtain the EGG signal; and

(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: 9/16/99  
September 16, 1999



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Linda S. Kahan  
Deputy Director for Regulations Policy  
Center for Devices and Radiological Health

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