DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 1999

3CPM Company, Inc.
c/o Daniel J. Manelli
Regulatory Consultant
2000 M. Street N.W., 7th Floor
Washington, D.C. 20036

Re: K984637
Evaluation of Automatic Class III Designation
The 3CPM EGG Machine

Dear Mr. Manelli:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the 3CPM EGG Machine that is intended for use as a diagnostic device that receives, records, and produces a visual display of the electrical signal produced by the stomach. This device is to be used to record electrogastrograms, as a component of a comprehensive clinical evaluation in patients with symptoms consistent with gastrointestinal motility disorders. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the 3CPM EGG Machine, and substantially equivalent devices of this generic type into class II under the generic name, Electrogastrography (EGG) System. This order also identifies the special controls applicable to this type of device.

FDA identifies this generic type of device as a gastroenterology-urology device under 21 CFR 876.1735, as an electrogastrography system, which 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.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Devices Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statue 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 (21 U.S.C. 360c(i)), 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 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device. 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** classifying the device.

On July 12, 1999, FDA filed your petition requesting classification of the 3CPM EGG Machine into class II. The petition was submitted under 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on July 2, 1999, automatically classifying the 3CPM EGG Machine in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the 3CPM EGG Machine into class I or II, it is necessary that the proposed class have sufficient regulatory 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, FDA has determined that the 3CPM EGG Machine can be classified in class II with the establishment of special controls. You may now market the device. The 3CPM EGG Machine is intended for use as a diagnostic device that receives, records, and produces a visual display of the electrical signal produced by the stomach. This device is to be used to record electrogastrograms, as a component of a comprehensive clinical evaluation in patients with symptoms consistent with gastrointestinal motility disorders. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device.

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

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) which 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 electrogastrography system they intend to market.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market the device, subject to the general controls provisions of the Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Carolyn Y. Neuland, Ph.D. at (301) 594-1220.

Sincerely,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health