DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2002

Mr. Steve Kay
Global QA/RA Manager
GE Marquette Medical Systems, Inc.
8200 West Tower Avenue
Milwaukee, Wisconsin 53223

Re: Reclassification Order:
Docket No. 97P-0350
Home Uterine Activity Monitor, Corometrics Model 770 Home Uterine Activity Monitoring System

Dear Mr. Kay:

This letter corrects our reclassification order to you for the Corometrics Model 770 Home Uterine Activity Monitor, dated originally January 5, 2001, and corrected on January 19, 2001, to state that a new premarket notification (510(k)) submission was not required for the above referenced device. We are now correcting this order to remove the patient registry as a special control. FDA has concluded that this requirement is not necessary to address the risks associated with the device for this indication.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for reclassification of the Corometrics Model 770 Home Uterine Activity Monitoring (HUAM) System that is intended for use in women with a previous preterm delivery to aid in the detection of preterm labor (PTL). FDA concludes that this device and substantially equivalent devices of this generic type, should be reclassified from class III into class II. This order, therefore, reclassifies the Corometrics Model 770 HUAM System, and substantially equivalent devices of this generic type into class II, under the generic name Home Uterine Activity Monitors, effective immediately. This order also identifies the special control applicable to the device as the FDA guidance document. You do not need a 510(k) premarket notification, and you may immediately begin commercial distribution of the reclassified device, the Model 770 HUAM.

FDA identifies this generic type of device, the subject of this reclassification, as follows:

1. A HUAM is a device intended for use in women with a previous preterm delivery to aid in the detection of preterm labor.

2. The HUAM is an electronic system for at-home antepartum measurement of uterine

contractions, data transmission by telephone to a clinical setting, and for data receive/display of the uterine contraction data at the clinic. The HUAM system comprises a tocotransducer, an at-home recorder, a modem, and a data receive/process/display computer/monitor.

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution prior to 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. Those devices remain in class III and require premarket approval, unless and until: (1) the device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act (21 U.S.C. 360c(f)(2)), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA); or (3) 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 regulations (21 CFR Part 807).

As you know, on August 15, 1997, FDA filed your petition requesting reclassification of Corometrics Model 770 HUAM system from class III into class II. The petition was submitted under section 513(f)(2) of the act, now section 513(f)(3) of the act, as amended by the FDAMA, and 21 CFR §860.134 of the agency's regulations. In accordance with section 513(f)(1) of the act, the HUAM was automatically classified into class III because the HUAM was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and had not been found substantially equivalent to a device placed in commercial distribution after May 28, 1976, which was subsequently reclassified into class II or class I. In order to reclassify the HUAM intended for use in women with a previous preterm delivery to aid in the detection of PTL into class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of safety and effectiveness of the device for its intended use.

Pursuant to 21 CFR §860.125 and §860.134, FDA consulted with the Obstetric and Gynecologic Devices Panel (the Panel). The Panel unanimously recommended that the HUAM for use in women with a previous preterm delivery to aid in the detection of PTL be reclassified from class III into class II because the Panel believes that special controls will provide reasonable assurance of the safety and effectiveness of the device. This recommendation was based on the information and data contained in the reclassification petition, on the summary and analysis of the data as set forth in the petition, on information presented during the open public hearing and open committee discussions of the meeting held on October 7, 1997, and on the Panel member's own personal knowledge of, and clinical experience with, the device.

The report and recommendation of the Panel were published in the Federal Register of July 30, 1999, 64 FR 41435 (enclosed) and interested persons were invited to comment by November 26, 1999,

(extended date). FDA received 5 comments in response to the notice of panel recommendation. The comments expressed concern about the several aspects of reclassification of the device and associated special controls (see the attached summary of comments and responses).

FDA agrees with the Panel's recommendation to reclassify the HUAM from class III into class II with FDA's guidance document identified as the special control. This decision is based on the administrative record which consists of the reclassification petition, the transcript and minutes of the October 7, 1997, meeting of the Panel, and all other information identified in this letter.

After review of the information submitted in the petition and consultation with the Panel regarding the reclassification petition, FDA has determined that the HUAM intended for use in women with a previous preterm delivery to aid in the detection of preterm labor as described and identified herein can be reclassified from class III into class II with the establishment of special controls. FDA developed a guidance document on HUAMs that serves as the special control. The guidance document addresses the various risks that were identified by FDA and the Panel that are pertinent to use of HUAMs. In particular, the guidance document addresses the bench testing and clinical study validation of the safety, performance, and effectiveness of the device, as well as labeling to describe the device's capabilities and discourage off-label use. FDA believes that class II with special controls provide reasonable assurance of the safety and effectiveness of the device.

FDA has identified the following risks associated with the use of the device: electrical shock and/or injury, skin irritation and sensitization, unnecessary evaluation and treatment, disabilities and psychological issues, and other risks from use in unproved patient populations. The potential risk of electrical shock is well understood, and can be mitigated by appropriate system design such as sufficient electrical isolation or other safety measures in accordance with applicable consensus standards as addressed by the guidance document. The risk of skin irritation and sensitization can be lessened, if it occurs, by a consensus standard for material safety as addressed by the guidance document. Unnecessary evaluation and treatment may result from an imprecise definition of PTL or failure of a HUAM to accurately depict uterine activity. Diagnosis of PTL is often difficult, and many times can only be confirmed retrospectively by the preterm delivery. To the extent possible, labeling can address appropriate use of the device and the adequacy of the design may be demonstrated with bench testing as addressed by the guidance document. Physical disabilities and psychological burdens may result from the clinical management of women diagnosed with PTL. Nonetheless, high risk pregnancy is often psychologically debilitating to the patient, and tocolytics may be prescribed for unmonitored women as well. The labeling, as prescribed by the guidance document, can address appropriate use of the device. This reclassification order as it applies to your HUAM is only for the following indication for use: women with a clinical history of previous preterm birth. As described in the special controls guidance document, you may not label or promote this monitor for any other indications for use.

The device is subject to the general control sections of the act, and any special controls (guidance document) identified under section 513(a)(1)(B) of the act (21 U.S.C. 360c(a)(1)(B)), including any performance standards promulgated under section 514 of the act (21 U.S.C. 360d). Thus, other

persons who intend to market this device must submit to FDA a premarket notification submission containing information on the HUAM they intend to market prior to marketing the device.

A notice announcing this reclassification 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, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

If you have any questions concerning this reclassification order, please contact Mr. Colin M. Pollard, at 301-594-1180.

Sincerely yours,

Daniel G. Schultz, M.D.
Deputy Director, Clinical
and Review Policy
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures
FR Notice (64 FR 41435)
Summary Comments and Responses