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Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors

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This document supersedes the draft document entitled Home Uterine Activity Monitors: Guidance for the Submission of 510(k) Premarket Notifications, dated July 30, 1999



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Obstetrics-Gynecology Devices Branch
Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation

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Preface

Public Comment:

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Such comments will be considered when determining whether to amend the current guidance.

After 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions may be submitted at any time for Agency consideration to Colin Pollard, HFZ-470. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Colin Pollard, HFZ-470.

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Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance For Home Uterine Activity Monitors

This guidance document represents the agency's current thinking on home uterine activity monitors. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

I. Background

This guidance document is a "special control" within the meaning of Section 513(a)(1)(B) of the Food, Drug, and Cosmetic Act. It describes the regulatory controls that FDA applies to manufacturers of home uterine activity monitors (HUAMs) for the purposes of demonstrating safety, effectiveness, and substantial equivalence. Designation of this guidance document as a special control means manufacturers of HUAMs, who follow the recommendations listed in this document before introducing their device into commercial distribution in the United States, will be able to market their device after they have submitted a premarket notification, referred to as a 510(k), and received a finding of "substantial equivalence" for their device. Manufacturers should comply with either the recommendations of this guidance or some alternate means that provide equivalent assurance of safety and effectiveness.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be approved/cleared for marketing. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that information is being requested that is not relevant to the regulatory decision for your pending application or that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

On March 9, 2001, FDA reclassified HUAMs from Class III (Premarket Approval) into Class II (Special Controls). The HUAM is a postamendments device and, as such, was automatically classified into class III. Reclassification of these devices may be initiated by FDA

under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act), or the manufacturer or importer of a device may petition the Secretary for the issuance of an order classifying the device in class I or class II. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

FDA received a petition for a HUAM on August 15, 1997. Consistent with the act and the regulation, FDA referred the petition to the Obstetrics and Gynecology Devices Panel (the Panel) on October 7, 1997, for its recommendation on the requested change in classification. The Panel voted in favor of the reclassification and FDA agreed. A Federal Register Notice was issued to this effect on July 30, 1999.

II. Scope

This guidance applies to home uterine activity monitors which conform to the following description and intended use.

A. Device Description

Common Name: Home Uterine Activity Monitor (HUAM)
Class: II
Classification Panel: 85
Product Code: LQK
Regulation number: 884.2730

B. Intended Use and Indications for Use

The home uterine activity monitor (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.

The HUAM is a prescription-use only system that is indicated for use, in conjunction with standard high risk care, for the daily at-home measurement of uterine activity in pregnancies ≥ 24 weeks gestation for women with a history of previous preterm birth. Uterine activity is displayed at a remote location to aid in the early detection of pre-term labor.

III. Risks to Health

FDA has identified five risks to health associated with this type of device. These risks are:

- Electrical shock and/or injury
- Skin irritation and sensitization (from abdominal belt or tocotransducer)
- Unnecessary evaluation and treatment (from over-diagnosis)
- Potential harmful effects from treatment with tocolytics

- Use on Unproven Patient Subpopulations (with shifted risk-benefit)

IV. Special Controls Guidance

FDA believes that the following controls, when combined with the general controls of the act, will provide a reasonable assurance of the safety and effectiveness of this type of device: labeling, design controls, clinical information, and a patient registry.

A. Labeling

Conformance to the labeling regulations and policies is necessary (see 21 CFR 807.87(e)). Appropriate labeling guidance documents are available through the Division of Small Manufacturer's Assistance (DSMA) at its toll-free number (800) 638-2041 or at its Internet address: http://www.fda.gov/cdrh/dsma/dsmamain.html.

HUAM labeling should follow the guidance below:

1. Indications for use

This HUAM is indicated for use, in conjunction with standard high risk care, for the daily at home measurement of uterine activity in pregnancies greater than or equal to 24 weeks gestation for women with a previous preterm delivery. Uterine activity is displayed at a remote location to aid in the early detection of preterm labor.

The following statements regarding limitations of HUAM effectiveness should immediately follow the indications for use statement; boxed with prominent placement:

This HUAM only monitors uterine activity and provides this information to the physician for assessment and, if necessary, intervention. This HUAM does not prevent the onset of preterm labor nor will it prevent the occurrence of preterm birth.

Clinical studies have shown that when a patient at risk for preterm labor is already enrolled in a daily nursing contact program, the HUAM does not provide any added effectiveness, i.e., a higher rate of detection of preterm labor over and above the detection rate associated with the daily nursing contact.

No widely-accepted controlled studies have been conducted that show that this device is effective at the early detection of preterm labor other than in patients with a previous preterm delivery.

2. Contraindications

There are no known contraindications to the use of this device.

3. Warnings

Depending on the specific monitor design, warning statement(s) may be necessary.

4. Precautions

Depending on the specific monitor design, precaution statement(s) may be necessary.

5. Instructions for Use

Both professional and patient instructions for use should be provided. At a minimum, the Instructions for use should include the following:

a. After prescription of the device by a physician, the patient should be educated regarding the signs and symptoms of preterm labor per standard high risk care.

b. The patient should receive instructions from a qualified medical practitioner regarding the proper operation of the device. These instructions should include the appropriate location for tocotransducer or sensor placement to facilitate uterine activity detection.

c. The patient should be instructed by a qualified medical practitioner to monitor her uterine activity as prescribed. Studies and device experience that were shown to be successful in earlier detection of preterm labor used the following parameters (which may be included in the labeling as guidelines for the practitioner):

- One or two one-hour monitoring sessions per day
- Use of the device in a reclining position
- Data transmission to clinician immediately following each session

Instruct the patient to contact the physician if she physically perceives uterine activity at any other time of the day. She may then be instructed to (a) monitor immediately or (b) come in to the clinic.

B. Design Controls

The Quality System Regulation addresses the following (among other things): Corrective and Preventive Actions or CAPA, Design Controls, Production and Process Controls, Management Controls, Facilities and Equipment Controls, Materials Controls, and Documents/Records/Change Controls. Design Controls ensure that design requirements address the intended use of the device, including the needs of the user and patient. Design controls generally include, but are not limited to the following documentation: risk management analysis, system architecture, design requirements, and verification and validation. Recommendations for the documentation of these processes are included in 510(k) section below.

C. Clinical Information

Submit results from a small clinical study (n=25) that is designed to show that the device produces tracings at the receiving station that are readable, i.e., that contractions are correctly perceived by the clinician. The study design should reflect the actual use scenario – use by subjects with appropriate risk factors, at the appropriate gestational age, in their own home, and after receiving applicable training. This objective should address the remaining performance issues of the device, namely, the recording and data transmission functions and usability by patients that cannot be addressed via bench testing.

D. Patient Registry

Patient registries provide a means to track outcome data and also to characterize the patient populations for which HUAMs are actually used. Patient registries should be designed in a manner that allows the manufacturer to obtain information about numbers of women who use the device, the fetal outcome, and whether the patient used a monitor during any previous pregnancies. In addition, the registry should record information that shows how the device is actually being prescribed by the clinical community, including instances, e.g., where the device is ordered for multiple gestation pregnancies or for women experiencing preterm labor for the first time. The registry may be designed to capture a sample of patients rather than all users; in that case, however, the structured sampling procedure should be consistent and the numbers sufficient to provide useful information about use and outcomes.

V. 510(k) Premarket Notification Recommendations

A. General Recommendations

Many decisions made during the design and development phase bear on the safety and effectiveness of the device. FDA has an interest in reviewing such design decisions, and those decisions should be documented in the design history file. Thus, your 510(k)

submission should include excerpts or "artifacts" from the design history which bear on safety and effectiveness.

In some cases, an FDA investigator might ask to review the same documents during a quality system inspection. The quality system inspector's interest is to assess the adequacy of your quality system, and the extent to which your firm is following its documented quality system processes. In a 510(k) review, FDA's interest is to determine whether the firm's engineering and clinical judgments concerning safety and effectiveness are reasonable.

Toward this end, your submission should include a risk management report. In addition, supporting documentation should be submitted to demonstrate that the results of risk management activities were carried over to the design. In every case, the supporting documentation should include a user manual, description of the system architecture, requirements documents for major system components, and selected verification and validation documents. Each of these items is described in the following paragraphs.

1. Risk Management Report

   Your submission should include a risk management report, summarizing the results of risk management activities pertaining to safety of the device. The risk management report should list identified safety hazards associated with the use of the device. For each hazard listed, the report should indicate initiating cause(s), the methods used to control risk, and the risk level before and after mitigation. FDA's review will be facilitated if the risk management report is cross-referenced to supporting documents, such as requirements documents, test procedures, and test results which show that specific risk control measures were successfully translated into device requirements and verified or validated as appropriate.

   The risk management report may be submitted in any reasonable format. For example, the information may be presented in tabular or narrative format, and risk levels may be expressed quantitatively or qualitatively as appropriate. The format you choose will probably be dictated by your firm's risk management process.

2. System Architecture

   Your submission should describe the major components of your system, and indicate how the functional requirements are allocated among them. This may be as simple as a block diagram listing the major functions performed by each system component.

3. Requirements Document(s)

   Each submission should include requirements documents (i.e., documents resulting from the design input process) which define the system functional, performance,

and interface characteristics in engineering terms. Your firm may refer to these documents as "system specifications," "design requirements," "requirements specifications," or another name. In many cases, there will be several such documents, covering the major hardware and software components of the system. For more information on requirements documents, see Section C of the FDA guidance document "*Design Control Guidance For Medical Device Manufacturers*" (Reference A).

FDA's interest in these documents is threefold. First, they provide objective evidence that risk control measures necessary to ensure safety have been translated into appropriate device requirements. Second, FDA needs to be assured that the requirements documents comprehensively characterize the intended use environment. Third, FDA needs assurance that those technical characteristics of the device that are critical to its clinical effectiveness are adequately described.

4. Verification and Validation Documents

FDA does not intend for you to submit voluminous verification and validation data. Rather, your submission should include a representative sample of documents to show that device requirements affecting safety and effectiveness have been verified or validated, as appropriate. Examples of such documents include:

- analyses
- test and inspection plans
- test and inspection procedures
- test and inspection reports
- verification and validation summaries

For more information on verification and validation documents, see Sections F and G of the FDA guidance document "*Design Control Guidance For Medical Device Manufacturers*" (Reference A).

5. Comparison to a Predicate Device for Substantial Equivalence

The Petition for Reclassification and the FDA's final rule on the HUAM provide an *identification* of this device (66 FR 14074). You may refer to those sources for a predicate comparison. Alternatively, as FDA clears 510(k)s for HUAMs, pursuant to the reclassification, those cleared HUAMs may also serve as predicate devices. Please refer to those documents for details on the predicate device.

B. Use of Industry Consensus Standards

You may simplify your submission, and facilitate its review by FDA, by using industry consensus standards that bear on preclinical safety and effectiveness. FDA has formally recognized a substantial number of such standards as providing reasonable assurance of

safety and effectiveness within their stated scope of applicability. See the FDA document "*Guidance for the Recognition and Use of Consensus Standards*" (Reference B) for details on the use of recognized standards. The basic outlines of the program are as follows:

- To the extent that your proposed device conforms to FDA-recognized standards, you usually need only submit a declaration of conformity in lieu of detailed safety and effectiveness data.

- If you have not completed your conformance assessment at the time of your submission, your declaration of intent may be sufficient to obtain approval.

- In some cases, it may be necessary to include specified information along with your declaration of conformity. For example, when the standard specifies a test method but provides no performance limits, you should describe and justify the performance limits you adopted for your device.

- Any omitted tests or deviations from the requirements of the chosen standard should be accompanied by appropriate justification.

You may also choose to use a standard that has not been recognized by CDRH. In this case, you should identify the standard, justify its applicability to your device, and describe how you applied the standard. For example, for a performance standard, you should describe the test method used to measure performance and provide or summarize test data.

C. Preclinical Concerns Specific to HUAMs

FDA has a number of concerns which are specific to home uterine activity monitors (HUAMs). In this section, we identify particular FDA-recognized standards that may be applicable, and discuss limitations and concerns about the applicability of such standards to HUAMs. We also discuss safety and effectiveness concerns which are not addressed by any known standard and which should be covered in your submission.

1. General Recommendations for Safety

Many HUAM safety issues are covered by an FDA-recognized standard, International Electrotechnical Commission (IEC) 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety, Amendment 1, 1991-11 Amendment 2, 1995-03. This standard covers a broad range of device hazards, including electrical safety, mechanical, excessive temperature, fire, liquid ingress, spillage, and cleaning. Manufacturers who rely on conformance to this standard should also conform to the collateral standards in the 60601 series, unless your submission explicitly states otherwise. The collateral standards include:

- IEC 60601-1-1: Medical Electrical Equipment - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems, 1992-06 Amendment 1, 1995-11 (General)

- IEC 60601-1-2: Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests.

- IEC 60601-1-4: Medical Electrical Equipment - Part 1: General Requirements for Safety; 4. Collateral Standard: Programmable Electrical Medical Systems

However, the scope of the IEC 60601 series of standards is limited to medical devices used by trained health care professionals in a clinical setting. Therefore, the portion of the HUAM system that is intended for use by patients in the home exceeds the scope of IEC 60601. Examples of potential problem areas posed by home use include a wider range of environmental conditions than normally encountered in the clinical setting, high variability in the training and education of users, and increased potential for close encounters with small children and pets. These and similar concerns, not covered by IEC 60601, should be addressed by your risk management report and supporting documentation.

2. Software

You should provide information on how software is implemented in your HUAM system. For additional information about software documentation in a 510(k), please refer to the FDA document "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*," (Reference C). In general, the software in HUAMs is considered to be a " minor" level of concern, as defined in the guidance. If Off-the-Shelf or 3rd party software is used, refer to the "*Guidance for Off-The-Shelf Software Use in Medical Devices*," (Reference D) for further guidance.

3. Waveform Accuracy

Since the toco pressure waveform represents a physiological process that is being evaluated, waveform accuracy is a key factor in establishing whether the device is clinically effective. From an engineering point of view, the gain accuracy, dynamic range, and frequency response of the toco pressure signal are all clinically significant parameters.

Home uterine activity monitors typically encode periodic samples of the toco pressure waveform. After digital transmission to the receiving station, the waveform is reconstructed and displayed. Thus, the system specifications should be allocated between the transmitter and the receiver, and allocated further among the analog and digital portions of the design. Finally, the performance

characteristics of the analog and digital sections should be matched to ensure that the sampling process does not introduce artifacts into the waveform.

Your submission should address these key engineering issues pertaining to waveform accuracy.

4. Data Integrity

Your submission should address the clinical significance of data transmission errors, and describe performance requirements for the data processing hardware, the modem, and the software algorithms that perform error correction and detection. Response of the system to noise, distortion, call-waiting tones, and other channel disruptions typical of the public switched telephone network environment should be covered. Assurance of Data Integrity may also need to address data corruption due to power fluctuations, user inputs, static data, switch debouncing, data archival, etc., which should be covered as necessary.

5. Material Safety

The tocotransducer and the abdominal belt that holds it in place contact the skin. Your submission should address the safety of the materials with this type of skin exposure, especially with respect to cytotoxicity, skin irritation, and sensitization. These issues are addressed by several FDA-recognized standards:

- ISO 10993-1: Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.
- ISO 10993-5: Biological Evaluation of Medical Devices Part 5: Tests for Cytotoxicity.
- ISO 10993-10: Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Sensitization.

6. Cleaning and Disinfection

Please provide information of how HUAM instrumentation will be provided to the patient so as to ensure that these devices are, at a minimum, in a clean and disinfected condition. If the manufacturer or clinician provides reprocessed HUAMs to patients, labeling should provide validated instructions for cleaning and disinfection between uses, using a cleaning/disinfection routine.

D. Clinical Information

Results from a small clinical validation study to show that the monitor executes some or all appropriate functions. See guidance in special controls section above.

E. Patient Registry

Describe the patient registry plan for this HUAM. If a structured sampling approach is used, provide adequate justification. Include samples of the data collection forms. For further guidance on this recommendation, contact the branch chief of the Obstetrics and Gynecology Devices Branch of the Office of device Evaluation at 301-594-1180.

VI. References

A. Design Control Guidance for Medical Device Manufacturers. Dated March 11, 1997. http://www.fda.gov/cdrh/comp/designgd.html (text) or http://www.fda.gov/cdrh/comp/designgd.pdf (pdf)

B. Guidance for the Recognition and Use of Consensus Standards. Dated February 19, 1998. http://www.fda.gov/cdrh/modact/k982.html (text)

C. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. Dated May 29, 1998. http://www.fda.gov/cdrh/ode/57.html (text) or http://www.fda.gov/cdrh/ode/software.pdf (pdf)

D. Guidance for Off-The Shelf Software Use in Medical Devices. Dated September 9, 1999. http://www.fda.gov/cdrh/ode/1252.html (text) or http://www.fda.gov/cdrh/ode/otssguid.pdf (pdf)