

Guidance for Industry and FDA Reviewers

Home Uterine Activity Monitors:
*Guidance for the Submission of
510(k) Premarket Notifications*

Draft Guidance – Not for Implementation

**This guidance document is being distributed for comment purposes only.
Draft released for comment on [release date as stated in FR Notice]**

This document supersedes the draft document titled Premarket Testing Guidelines for Home Uterine Activity Monitors, dated March 31, 1993.



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, Ear, Nose and Throat 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.

Additional Copies:

World Wide Web/CDRH home page at <http://www.fda.gov/cdrh> or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 820 when prompted for the document shelf number.

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, regulations, or both.

Home Uterine Activity Monitors: *Guidance for the Submission of 510(k) Premarket Notifications*

This guidance document describes a means by which home uterine activity monitors may comply with this requirement of special controls for class II devices. Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate home uterine activity monitor should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

I. Device Description

Common Name: Home Uterine Activity Monitor (HUAM)
Class: II
Classification Panel: 85
Product Code: LQK
Regulation number: 884.xxxx

II. 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 tokodynamometer, 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 PTL.

III. Preclinical Data

A. Electrical Safety Testing

Any appropriate standard for electrical safety may be used. You may provide a *Declaration of Conformity* to International Electrotechnical Commission (IEC) 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety, Amendment 1, 1991-11 Amendment 2, 1995-03. Refer to “Guidance for the Recognition and Use of Consensus Standards” for additional details on how to prepare a declaration of conformity.

If you choose to use another standard, please identify the standard by name, justify the use of the standard for this type of device, and provide a test report of the tests performed.

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

B. Electromagnetic Compatibility

Any appropriate standard for electromagnetic compatibility may be used. You may provide a *Declaration of Conformity* to International Electrotechnical Commission (IEC) 60601-1-2: Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests. Refer to “Guidance for the Recognition and Use of Consensus Standards” for additional details on how to prepare a declaration of conformity.

If you choose to use another standard, please identify the standard by name, justify the use of the standard for this type of device, and provide a test report on the tests performed.

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

C. Software

Provide information on how software is implemented in your HUAM system. For additional information about software documentation in a 510(k), please refer to CDRH’s “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”. In general, the software in HUAMs is considered to be a “minor” *level of concern*, as defined in the guidance.

D. Material Safety

The tocotransducer and the abdominal belt that holds it in place contact the skin. Please provide information on the safety of the materials with this type of skin exposure, especially with respect to cytotoxicity, skin irritation, and sensitization. Any appropriate standard for material safety may be used. You may provide a *Declaration of Conformity* to International Standards Organization (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; and ISO 10993-10: Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Sensitization. Refer to “Guidance for the Recognition and Use of Consensus Standards” for additional details on how to prepare a declaration of conformity. This standard only specifies the test protocols; please submit summaries of the test results.

If you choose to use another standard, please identify the standard by name, justify the use of the standard for this type of device, and provide a test report on the tests performed.

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

E. Bench Validation Testing

Please submit the results of other non-clinical testing to verify and/or validate the intended HUAM functions. These tests should address the intended operational characteristics of the HUAM (independently or in combination with clinical validation studies), i.e., collection, storage, and transmission of data. Appropriately designed bench testing will ensure that uterine activity, and contractions in particular, are accurately measured and displayed by the device, thereby minimizing false positives associated with the device. Test procedures should be tailored to the individual features of your HUAM.

IV. Clinical Data

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.

V. Patient Registries

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 carry a sample of patients rather than all users; in that case, however, the sampling procedure should be consistent and the numbers sufficient to provide useful information about use and outcomes.

VI. 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 [FR citation]. 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.

VII. 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 instructions for disinfection between uses, with a cleaning/disinfection routine such as washing with a mild soap followed by a low level disinfection (i.e., cidex or alcohol wash).

VII. Labeling

Conformance to the labeling regulations and policies is necessary (see 21 CFR 807.87(e)). Appropriate labeling guidances 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/dsmamain.html>.

The following specific labeling requirements for home uterine activity monitors also apply:

A. Indications for use

The indications shall be stated as follows (or using equivalent language): "This device 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."

B. Contraindications

There are no known contraindications to the use of this device. However, there is also no evidence to show that this device prevents preterm delivery.

C. Warnings

Warnings are specific to the design and operation of the device and should be worded accordingly. A general precaution should provide statements to the effect that:

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.

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Clinical data from many studies has shown that the HUAM, when coupled with intensive daily nursing contact, does not provide additional information for the early detection of preterm labor.

D. Precautions

Precautions are specific to the design and operation of the device and should be worded accordingly. A general warning should provide statements to the effect that:

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.

E. Instructions for Use

Both professional and patient instructions for use are required. At a minimum, the following is required for Instructions for use:

1. 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.
2. 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 tocodynamometer or sensor placement to facilitate uterine activity detection.
3. The patient should be instructed by a qualified medical practitioner to monitor her uterine activity as prescribed. Studies that were shown to be successful in earlier detection of preterm labor used the following requirements:

One or two one hour monitoring sessions per day

Use of the device in a reclining position

Data transmission following each session

Instruct the patient to contact the physician if uterine activity is perceived at other times of the day – may then be instructed to monitor immediately