

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-1817]

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Certifier	Monica Oliver

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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors." This guidance describes the special controls FDA believes will provide reasonable assurance of the safety and effectiveness of these devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying the home uterine activity monitors (HUAM's) from class III to class II.

**DATES:** Submit written comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the

**SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

NAD-2

**FOR FURTHER INFORMATION CONTACT:** Colin M. Pollard, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This guidance document describes a means by which manufacturers of HUAM's may comply with the requirements of special controls for class II devices. Designation of this guidance as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate HUAM 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.

The guidance document addresses such areas as: Intended use and indications for use; labeling; design controls; clinical data; patient registry; preclinical data including electrical safety testing, electromagnetic compatibility, software, device accuracy, material safety, and cleaning and disinfection.

This guidance document was issued for public comment in the **Federal Register** of July 30, 1999 (64 FR 41443), as a draft guidance entitled "Home Uterine Activity Monitors; Guidance for the Submission of 510(k) Premarket Notifications." The document has been modified from the original draft version for purposes of clarity and adding detail regarding the device description, bench testing, and design controls.

**II. Significance of Guidance**

This guidance document represents the agency's current thinking on premarket notifications for HUAM's. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), and published the final rule which set forth the agency's regulations for the development, issuance, and use of guidance documents (65 FR 56468, September 19, 2000). This guidance document is issued as a Level 1 final guidance in accordance with the GGP regulations.

### **III. Electronic Access**

In order to receive "Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors" via your fax machine, call the CDRH Facts-on-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (820) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes "Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>.

### **IV. Comments**

Interested persons may, at any time, submit written comments regarding the guidance to the Dockets Management Branch (address above). Such comments will be considered when determining whether to amend the current guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the

docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 1/31/01  
January 31, 2001.

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

Linda S. Kahan

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Ronnie Oliver

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