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Certifier	J. W. Johnson

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-1817]

Home Uterine Activity Monitors Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Home Uterine Activity Monitors; Guidance for the Submission of 510(k) Premarket Notifications." Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of the panel recommendation to reclassify home uterine activity monitors (HUAM's) into class II (special controls) and FDA's tentative findings. FDA agrees that these monitors should be reclassified in class II, and the guidance that is the subject of this notice of availability is one of the special controls that FDA believes will provide reasonable assurance of the safety and effectiveness of these devices.

DATES: Submit written comments by (*insert date 90 days after date of publication in the Federal Register*).

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance entitled "Home Uterine Activity Monitors; Guidance for the Submission of 510(k) Premarket Notifications" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on the “Home Uterine Activity Monitors; Guidance for the Submission of 510(k) Premarket Notifications” to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kathy Daws-Kopp, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180, ext. 132.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document describes a means by which HUAM’s may comply with the 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 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; preclinical data including electrical safety testing, electromagnetic compatibility, software, material safety, and bench validation testing; clinical data; cleaning and disinfection; and labeling.

In addition to this guidance document, FDA is also proposing that patient registries be a special control for HUAM’s.

II. Significance of Guidance

This guidance 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), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive "Home Uterine Activity Monitors; Guidance for the Submission of 510(k) Premarket Notifications" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (820) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes "Home Uterine Activity Monitors; Guidance for the Submission of 510(k) Premarket Notifications," 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, on or before (*insert date 90 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments regarding this draft 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. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

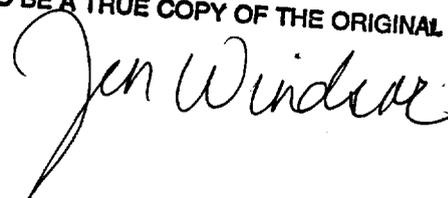
Dated: 6/30/99

June 30, 1999



Linda S. Kahan
Deputy Director for Regulations Policy
Center for Devices and Radiological Health

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



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