

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer 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. This guidance will be updated in the next revision to include the standard elements of GGP's.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**DATE:** September 6, 1996

Dear Manufacturers of Prescription Home Monitors for Non-Stress Tests:

This letter is to advise you of a change in the regulatory requirements for prescription monitors designed for home non-stress testing (NST).

As you may know, we previously have advised manufacturers that home use NST monitors are class III devices and must have an approved premarket approval application (PMA) in order to place the device into commercial distribution, in the United States. The PMA would have been expected to address questions about the clinical implications of home NSTs, as well as questions about monitor performance in the home environment and the ability of at-risk pregnant women to use the monitor properly to obtain NSTs that can be evaluated.

As a result of our efforts to streamline our regulatory requirements, we have concluded that the change in indication from performing NSTs in the physician's office or clinic to performing the same test in the home may be answered in the context of a 510(k) premarket notification. The predicate device for comparison is the pre-Amendments Class II antepartum monitor used to perform NSTs in the physician's office or clinic. In general, a 510(k) would be expected to provide appropriate bench testing to establish performance under home use conditions, as well as the results from a study to show that at-risk pregnant women can use the device properly and that accurate NST data can be adequately transmitted to the office or clinic.

The Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices (DRAERD) developed guidance for preparing a 510(k). This package on 510(k) content and format, entitled "Explanation for Items in DRAERD Premarket Notification 510(k) Screening Checklist", is enclosed. In addition, the Division of Small Manufacturers Assistance (DSMA) can be contacted at (800) 638-2041 or (301) 443-6597 to request a copy of a manual entitled "Premarket Notification 510(k): Regulatory Requirements for Medical Devices."

You may not market this device until you have adequately provided the information described above and required by 21 CFR 807.87, and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you may be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If you are developing or plan to develop a home NST monitor for distribution in the United States, you are strongly encouraged to contact the

Obstetrics and Gynecology Devices Branch to discuss the information and test data needed to support the 510(k). If you have any questions, please contact Mr. Colin M. Pollard at 301-594-1180.

Sincerely yours,

Philip J. Phillips  
Deputy Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number & Device Name \_\_\_\_\_

Company \_\_\_\_\_

ITEM	PRESENT		MORE
	<u>Yes</u>	<u>No</u>	<u>NEEDED</u> <u>(Y/N/?)</u>
<b>1. General information ( i.e., trade &amp; classification name, Est. Reg. No., device class, meets special controls or a performance standards, etc.)</b>	—	—	—
<b>Reason for 510(k) - new device or modification</b>	—	—	—
<b>Identification of legally marketed equivalent device</b>	—	—	—
<b>Truthful and accurate statement</b>	—	—	—
<b>SMDA 510(k) <u>summary</u></b>	—	—	—
<b>2. Proposed Labeling, Labels, Advertisements</b>	—	—	—
<b>Description of new device/modification</b>	—	—	—
<b>Intended use statement</b>	—	—	—
<b>Diagrams, Engineering Drawings, Photographs</b>	—	—	—
<b>Indication for Use Statement</b>	—	—	—
<b>3. Comparison of similarities/differences to named legally marketed equivalent device</b>	—	—	—
<b>Equivalent Device Labeling, Labels, Advertising</b>	—	—	—
<b>Intended use of equivalent device</b>	—	—	—
<b>4. List of all patient contacting materials in new device</b>	—	—	—
<b>Comparison of materials to equivalent device</b>	—	—	—
<b>5. Biocompatibility information/data for patient contacting materials, OR</b>	—	—	—
<b>Certification - identical material/formulation</b>	—	—	—
<b>6. Performance data: Bench data</b>	—	—	—
<b>Animal data</b>	—	—	—
<b>Clinical data</b>	—	—	—
<b>7. Sterilization information</b>	—	—	—
<b>8. Software validation &amp; verification</b>	—	—	—
<b>9. If Class III, Class III Certification &amp; Summary</b>	—	—	—
<b>10. If kit, kit certification</b>	—	—	—

**Explanation  
for Items in  
DRAERD Premarket Notification 510(k)  
Screening Checklist**

The Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices (DRAERD) of the Office of Device Evaluation (ODE) has initiated a screening program for all 510(k) premarket notifications received in the division. The purpose of this screening program is to provide the submitter of a 510(k) immediate feedback on basic administrative completeness of the initial submission before we begin our technical review. In the past, a majority of the submissions received in DRAERD were found to be lacking in basic information necessitating requests for additional information. These requests for additional basic information have resulted in delays for both the 510(k) submitter and the Food and Drug Administration (FDA).

Below is an explanation of each item on the screening checklist. There are three (3) columns of "blanks" with the first or second column having a "check mark," and the third having a "Y" (for yes), a "N" (for no), or a "?" (for don't know or unknown). A person submitting a 510(k) should look at the "Needed (Y/N/?)" column to see what additional basic information needs to be submitted. In addition, a specific item may be circled if only that item is missing. If the third column indicates a "?" (mainly applicable for item number 6, Performance data), we can not at this time determine if this information is needed. If you already have any information on a "?" item, it is suggested that you submit it as it will make the 510(k) more complete and may eliminate a later request for additional information. There may also be comments in the margin on the right side of the checklist.

**Checklist items:**

- 1. General information includes the following:**
  - a. applicant's name, signature and date, address, contact person and telephone number;**
  - b. a table of contents, listing of tabs and appendices, and appropriate pagination;**
  - c. the device name (trade or proprietary name and the common or usual name);**
  - d. the classification name;**
  - e. the establishment registration number, if applicable, of the owner or operator submitting the premarket notification;**
  - f. the address of the manufacturing facility/facilities and, if appropriate, the sterilization site(s);**

- g.** the class in which the device has been placed under section 513 of the act, and, its appropriate panel, if known, or, if the submitter determines that the device has not been classified, a statement of that determination and the basis for that determination;
- h.** action taken by the submitter to comply with the requirements of the Federal Food, Drug, and Cosmetic Act (act) under section 514 performance standards or section 513 special controls;
- I.** the reason for the premarket notification - a new device or a modification to an existing device (if modification, provide the 510(k) number for that device, if applicable);
- j.** an identification of the legally marketed device to which you claim equivalence. If known, provide the equivalent device's 510(k) number; and,
- k.** a statement that the submitter believes, to the best of his knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.
- l.** The Safe Medical Devices Act of 1990 (SMDA) requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), or (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement).

The content and format of a 510(k) summary can be found in Section 21 CFR 807.92. This Section states the following:

(a) A 510(k) summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence. FDA will accept summaries as well as amendments thereto until such time as FDA issues a determination of substantial equivalence. All 510(k) summaries shall contain the following information:

- (1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;
- (2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;
- (3) An identification of the legally marketed device that the submitter claims equivalence. A legally marketed device to which a new devices may be compared for a determination of substantial equivalence is a device that was

legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process;

- (4) A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical characteristics of the device, such as device design, material used, and physical properties;
  - (5) A statement of the intended use of the device that is subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled; and
  - (6) If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section.
- (b) 510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information:
- (1) A brief discussion of the nonclinical tests submitted, referenced or relied on in the premarket notification submission for a determination of substantial equivalence;
  - (2) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety and effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing

relevant to a determination of substantial equivalence; and

- (3) The conclusions drawn from the nonclinical and clinical tests that demonstrate the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section.
- (c) The summary should be in a separate section of the submission, beginning on a new page and ending on a page not shared with any other section of the premarket notification submission, and should be clearly identified as a "510(k) summary."
- (d) Any other information reasonably deemed necessary by the agency.

The content and format of a 510(k) statement can be found in Section 21 CFR 807.93. This Section states the following:

(a)(1) A 510(k) statement submitted as part of a premarket notification shall state as follows:

I certify that, in my capacity as (the position held in company by person required to submit the premarket notification, preferably the official correspondent in the firm), of (company name), I will make available all information included in this premarket notification on the safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(2) The statement in paragraph (a)(1) of this section should be signed by the certifier, made on a separate page of the premarket notification submission, and clearly identified as "510(k) statement."

(b) All requests for information included in paragraph (a) of this section shall be made in writing to the certifier, whose name will be published by FDA on a list of premarket notification submissions for which substantial equivalence determinations have been made.

(c) The information provided to requestors will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61 of this chapter.

2. Proposed labels, labeling, advertising and/or promotional materials, and specifications sufficient to describe the new device/modification, its intended use, and directions for use, as appropriate. The label of most device packaging must bear the caution statement as



outlined in 21 CFR 801.109 (b)(1): "CAUTION: Federal law restricts this device to sale by or on the order of a physician." Guidance on labeling issues is provided in ODE Bluebook Memo G91-1, "Device Labeling Guidance" dated March 8, 1991. To obtain a copy of this guidance, see below. Service manuals, engineering diagrams, drawings and/or photographs are usually necessary. Manufacturing information may be necessary.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. (See attached Optional Format 1-2-96.) This indication for use statement should be an exact copy of the indication for use section in your device labeling.

3. A comparison table and discussion indicating how the device is similar to and different from other products of comparable type, that are legally marketed in the United States, accompanied by data to support the statement. Legally marketed devices are those device(s) on the market before May 28, 1976, (pre-amendments), or devices found "substantially equivalent" after 1976 through the 510(k) process. If this 510(k) is for a modification to a device, describe the modifications. It is helpful and time saving to re-supply information from the original submission (i.e. drawing, specifications, etc.) rather than just supplying the reference 510(k) number for FDA to look up the information. This information should include an identification of the substantially equivalent device(s), its intended use, its specifications, labels, labeling and advertising and/or promotional materials.
4. For patient contacting devices, a list of all materials used in the new/modified device with a comparison of these materials to the device to which you claim equivalence. You must specifically identify the materials; indicating "silicone" or "polyvinyl chloride" is not sufficient. Formulation information should be supplied for all polymers.
5. For patient contacting devices, biocompatibility information and/or data on the device materials. See the Tripartite Biocompatibility Guidance document for the appropriate testing to satisfy this requirement. In general, all testing should be on sterilized final devices. Alternatively, we may accept a certification from you that the exact same material and formulation is used in this new/modified device as was used in the device to which you claim equivalence.
6. Some devices and device modifications require performance data in order to determine equivalence. Performance data should be compared to the performance of the device to which you claim equivalency. Performance data includes all bench, animal, and clinical data collected with the new device/modification. Performance data include objectives, test set-up, protocol, results, discussion of results, appropriately supporting device specifications, and conclusions.
7. Sterility information, if labeled as sterile, includes the method of sterilization; the sterility assurance level (SAL); the method used to validated the sterilization cycle; if ethylene oxide sterilization is used, the residues levels for ethylene oxide (EtO), ethylene chlorohydrin

(EtCh), and ethylene glycol (EtG); if radiation sterilization is used, the dose delivered; a description of the packaging, including materials; and if labeled as non-pyrogenic, provide the method used to make that determination and provide the sensitivity of the pyrogen assay used.

8. A report on software/firmware requirements, development, validation and verification is needed for all computer controlled devices dependent on software. A software release number should be indicated. Hardware validation and verification may also be required. The appropriate testing information should be submitted. This information is contained in Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review.
9. The SMDA also requires that any person who asserts that a device is substantially equivalent to a class III device to (1) certify that he/she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, and (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification).

If claiming substantial equivalence to a Class III device, provide the following as described under Section 513(f)(3) of the act:

"I certify that, in my capacity as [The Position Held In Company], of [Company Name], I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for the [Type Of Device]. I further certify that I am aware of the types of problems to which the [Type Of Device] is susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems about the [Type Of Device] is complete and accurate:

[NUMBER AND LIST SEPARATELY EACH TYPE OF PROBLEM AND ITS CAUSES]

Attached is a bibliography, or other citation, of the materials upon which the above summary is based."

Printed name of person required to submit 510(k):

Signature of person required to submit 510(k):

Title of person submitting 510(k):

Name of Company:

Date:

10. If this 510(k) is for a kit, a certification or other information is required (see attachment).

Copies of all guidance documents may be obtained from the Division of Small Manufacturers Assistance, CDRH, FDA, at 800-638-2041 or 301-443-6597.

Attachments

510(k) Number (if known): \_\_\_\_\_

Device Name: \_\_\_\_\_

Indications for Use:

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-the Counter Use: \_\_\_\_\_

(Optional Format 1-2-96)

3/14/95

### **Kit Certification and Information for Kit 510(k)s**

**For review purposes of a premarket notification (510(k)) for a kit, please provide the certification stated below:**

**I certify that the following components of my kit are either (1) legally marketed pre-amendments devices, (2) exempt from premarket notification (consistent with the exemption criteria described in the classification regulation(s) and the limitations of exemptions from Section 510(k) of the act (e.g., 862.9), or (3) have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is to be intended (i.e., I am not claiming or causing a new use for the component(s)).**

**I further certify that these components are not purchased in "bulk", but are purchased in finished form, i.e., they are packaged, labeled, etc., consistent with their pre-amendments, exemption, or premarket notification criteria and status.**

**If you cannot make the above referenced certification statement (first paragraph) for each component of your kit, you must itemize the components without a pre-amendments, exemption, or premarket notification status. In this case we will continue our premarket notification review of these components of your kit.**

**If you cannot make the above referenced certification statement (second paragraph) for each component of your kit, you must itemize these components, state whether they are pre-amendments, exempt, or have been found substantially equivalent through the premarket notification process, and describe how you further process them (e.g., sterile, package/repackage, label/relabel, etc.).**

**If your kit contains examination gloves which are purchased in bulk, your submission must contain the following:**

- a. data demonstrating or certification that the final finished sterile examination gloves in the kit meet the American Society for Testing and Materials (ASTM) standards for rubber examination gloves, ASTM D 3578-77 (Reapproved 1991); and,**
- b. data demonstrating or certification that the final finished sterile examination gloves pass the FDA 1000 milliliter water leak test in accordance with the sample plan and test method published in the FEDERAL REGISTER (55 FR 51254-51258).**

**If the device kit contains components which are subject to regulation as drugs, a substantially equivalent determination will not apply to the drug component(s) of the device. For information on applicable Agency requirements for marketing the drug component(s) in the kit, it is suggested that you contact the Center for Drug Evaluation and Research, Division of Drug Labeling Compliance, at (301) 594-0063. Correspondence should be addressed as follows:**

**Director, Division of Drug Labeling Compliance (HFD-310)  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857**

**If the kit contains sutures, provide evidence that the sterilant does not come into contact with the sutures during sterilization of the kit. Based on the evidence submitted, FDA will conclude if the sutures are or are not further processed. Inclusion of the sutures as components in your kit requires you to comply with the following conditions:**

- a. The labeling, packaging, and method of sterilization of the sutures you have listed cannot be changed without prior notification, review, and approval by FDA.**
- b. The suppliers of the sutures used in your kit cannot be changed without prior notification, review, and approval by FDA.**