# Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers (Text Only)

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.

March 1993

# GUIDANCE ON THE CONTENT OF PREMARKET NOTIFICATION [510(K)] SUBMISSIONS FOR CLINICAL ELECTRONIC THERMOMETERS

## I. INTRODUCTORY INFORMATION

### A. Scope

This document establishes the 510(k) review requirements for clinical electronic thermometers. Examples of devices within this generic type include devices which measure oral, axillary, rectal, or tympanic temperature utilizing a number of methods. The thermometer may or may not include separate disposable probe covers.

EXCLUSIONS

This guidance does not address submissions for clinical mercury thermometers or clinical color change thermometers (as described in 21 CFR 880.2900 and 880.2920, respectively)

### B. Purpose

This guidance is intended to:

1. assist persons (manufacturers, distributors, or importers) in organizing premarket notifications for clinical electronic thermometers;

2. achieve consistency in meeting of requirements and in the presentation of information; and

3. guide FDA review staff in conducting and documenting the review of premarket notifications for clinical electronic thermometers.

### C. Definitions

1. Clinical Electronic Thermometer: described in FDA regulation, 880.2910, as "a device used to measure the body temperature of a patient by means of a transducer

coupled with an electronic signal amplification, conditioning, and display unit. The transducer may be in a detachable probe with or without a disposable cover."

2. Accuracy: the degree to which the measurements from the device agree with the "true" values as would be measured by some other standard device, such as a thermocouple device calibrated against NIST Standards or other accepted national standards.

3. Probe: an assembly, including the transducer, used to position the transducer in the specific location at which the temperature is to be determined.

4. Radiation Thermometer: a device used to measure the temperature of a target body part based upon radiation emitted from the target part (e.g., an infrared tympanic thermometer).

5. Transducer: a component that provides a measurable output (e.g., resistance) as a function of temperature.

6. Precision: the degree to which the temperature is measured and represented.

7. Intended Use: the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by their expressions or may be shown by the circumstances surrounding the distribution of the device. The objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such representatives. It may be shown by the offering or the using of the device, with the knowledge of such persons or their representatives, for a purpose for which it is neither labeled nor advertised ( 801.4). Some use conditions for thermometers may include reusable, oral, axillary, rectal and typmanic measurements, and home use.

8. Abbreviations:

ANSI - American National Standards Institute
ASTM - American Society for Testing and Materials
CDRH - Center for Devices and Radiological Health
CFR - Code of Federal Regulations
DSMA - Division of Small Manufacturers Assistance
FDA - Food and Drug Administration
FR - Federal Register
IEC - International Electrotechnical Commission
HIMA - Health Industry Manufacturers Association
NIST - National Institute of Standards and Technology
ISO - International Organization for Standardization
OCS - Office of Compliance and Surveillance
ODE - Office of Device Evaluation
SMDA - Safe Medical Devices Act of 1990
UL - Underwriters Laboratory

D. General Principles Regarding Presentation of Data

1. Editorial Considerations: The 510(k) should be carefully edited, as well as scientifically reviewed before it is submitted to FDA. It should be proofread to assure that all pages/sections are included and are properly indicated, consecutive, distinctly copied, and legible.

2. Abbreviations: Standard abbreviations acceptable to a significant peer reviewed journal should be used wherever possible. All other abbreviations should be identified at the beginning of each section in which they are used or in footnotes to tables and graphs.

3. Data Availability: This document outlines typical circumstances of data review. It is not possible to anticipate all situations that may require FDA review. Thus, those submitting applications should be aware that they may be asked to submit additional data, to present data in another format or to provide more detailed explanations of the information submitted, if required to establish equivalence.

   Applicants should keep data used for the 510(k)

submission on file in a controlled and well-organized format. This will allow the applicant to expeditiously supply FDA with additional information or analysis if required. Errors in data that are identified by the applicant after submission to FDA should be brought to FDA's attention immediately.

4. Tables and Graphs: Well-constructed tables are fundamental to the reporting and evaluation of data. All tables should be clearly identified and captioned with symbols keyed to a footnote or accessible reference page that adequately indicates the nature of the data.

   Graphs should supplement, not replace, data tables. They should be of a high quality.

5. Published Literature: Published methods or data referenced in study reports should be made available to FDA upon request. Reprints of other referenced published reports or data should also be made available to FDA upon request. All referenced reports and data should be summarized including an explanation how it relates to the current submission. Reference citations should be complete (e.g., title, author, volume, year).

6. Protocols and Data Analysis:

   Test reports must include the protocol (objectives, precise description of materials, experimental methods, controls), observations, statistical methods and analyses, conclusions and comments. Do not submit raw data. Additional specific directions on protocols are included in sections that follow.

7. Reference to Submitted Data:

   In support of the 510(k), the applicant may reference any information previously submitted to FDA. If the applicant did not submit the referenced data he must provide, or have the submitter provide to FDA, a letter of authorization. Often, if the data are not extensive,

resubmitting data in the 510(k) will facilitate the review of the document.

E. Document Availability

The following documents are available from DSMA [(800)638-2041 or (301)443-6597]:

Tripartite Biocompatibility Guidance for Medical Devices

ODE Blue Book Memorandum #K90-1: 510(k) Sterility Review Guidance

II. CONTENT AND ORGANIZATION OF INFORMATION IN A 510(K) FOR A CLINICAL ELECTRONIC THERMOMETER

A. Cover Letter

The submission shall have a signed cover letter providing the following information described in 807.87 (Information required in a premarket notification submission):

1. The thermometer's trade or proprietary name.

2. Common Name: Oral Thermometer, Tympanic Thermometer, etc.

3. Classification name: Clinical Electronic Thermometer

4. The establishment registration number, if applicable, or the sponsor, owner or operator submitting the premarket notification

5. Class: II
Panel: 80
Procode: FLL - clinical electronic thermometer

6. A statement explaining the purpose of the submission (e.g., new device, significant modification of device previously found equivalent (new intended use, material, or manufacturing process, etc.)). Refer to 807.87(g) for additional information regarding changes to devices. The change may require some or all of the information

needed for a new device. Please supply the previous 510(k) number(s), if applicable.

7. A brief statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution.

8. Name, address, and phone number of a U.S. contact person, if available.

B. Labels and Labeling

1. The submission shall contain proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for use. Labels include the information affixed directly to the device or its container or packaging. Labeling also includes professional or patient package inserts, and any other information that accompanies the device.

2. The labeling must meet the requirements of 21 CFR Part 801 as it relates to a determination of intended use. ODE will concentrate on the following portions of Part 801:

   Subpart A, 801.4 and 801.5, related to intended uses and adequate directions for use; and

   Subpart B, 801.109 and 801.116, related to prescription devices and commonly known directions.

   Other provisions of Part 801 are deferred for review to CDRH/OCS Device Labeling Compliance Branch.

3. Labeling for the clinical electronic thermometer should include, if applicable:

   a. the type(s) of temperature measurements (e.g., oral, axillary, tympanic, etc.) which can be made by the thermometer as indicated in the statement of

intended use (see D.2);

b. a list of device specifications including, but not limited to: temperature range, accuracy, and precision;

c. the ambient temperature environment (range) in which the device may be used;

d. adequate directions for use for all possible functions of the device;

e. identification of compatible probe covers and instructions on their use and/or instructions on how to clean and disinfect or sterilize the device between uses;

f. instructions for proper maintenance of the device including a recalibration schedule and recalibration instructions;

g. instructions for interpreting the device output with regard to core body temperature; and

h. the time required to obtain a steady state reading.

C. Standards

Listed are some, but not all, of the standards related to clinical electronic thermometers:

1. ASTM E1112-86 Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature.

2. ASTM E1104-86 Standard Specification for Clinical Thermometers Probe Covers and Sheaths

3. UL 544 Standards for safety, medical and dental equipment

4. IEC 601-1/ANSI ES1-1985 Safe Current Limits for Electromedical Apparatus

The applicant may certify that the device meets a standard. The applicant then is obliged to comply with the standard and maintain documentation of tests showing that the device meets the standard. Certification of meeting a specific standard and reference to standards in the 510(k) may reduce the documentation needed in the 510(k) submission. This is noted in pertinent sections.

D. Device Description

The applicant must submit a complete description of the device, including all models and variations.

1. Provide a labeled representation of the device in sufficient detail to facilitate the evaluation of the nature and operation of the device (e.g., photographs, detailed drawings, or engineering drawings). If the labeling already includes sufficient illustrations of the device, refer to the labeling.

2. Provide a clear statement of the intended use(s) of the thermometer.

    a. Specify the type(s) of temperature measurements (e.g., oral, axillary, tympanic) which can be made by the thermometer.

    b. Describe any specific use of this device other than for the type(s) of temperature measurements as indicated in 2.a. above.

3. Provide the following information for the device. The applicant may refer to relevant standards.

    a. Physical Specifications

    (1) Components: Identify and describe all major components or component groups and give dimensions.

Each component/component group should be identified as reusable or disposable. Identify any component/component group which contacts the patient tissue or fluid and the type of tissue/fluid contacted.

(2) Sensor: Describe the sensor/transducer which is used to measure temperature.

(3) Signal Processing and Display: Provide a qualitative description of the signal processing and display components and their capabilities.

(4) Power Requirements: Describe the energy/power requirements and characteristics. Indicate if the device meets UL 544. If not, describe how.

(5) Materials: Identify the basic materials of construction. Provide the chemical formulation of all materials which contact patient tissue or fluids. If probe covers are included in this submission, identify their materials of construction.

b. Operational Specifications

(1) Temperature Range: Provide the temperature range of the device.

(2) Ambient Temperature Environment: Provide the ambient temperature range in which the device may be operated.

(3) Accuracy: Provide the accuracy over the entire temperature range specified for the device. The effects of air currents, over the entire useful temperature range specified, on accuracy should also be provided.

(4) Precision and Repeatability: Describe the precision and repeatability of measurements over the

temperature range specified. The effects of air currents, over the entire useful temperature range specified, on precision and repeatability should also be provided.

(5) Algorithms: If applicable, provide the model and algorithms used for the conversion of temperatures (e.g., tympanic to core).

(6) Time: Indicate the time required for the device to obtain a steady state reading.

(7) Other Capabilities: Describe any other capabilities the device may possess.

c. Biological Specifications

State the biocompatibility category for all patient tissue and fluid contacting components and materials per the draft ISO 194 Biocompatibility Standard or the Tripartite Biocompatibility Guidance.

E. Descriptive Comparison to a Legally Marketed Device

Identify a legally marketed electronic thermometer to which substantial equivalence is claimed. (If possible, identify the 510(k) number(s).) More than one thermometer can be listed, but the device(s) chosen should be as close in intended use and technology to the new device as possible. Provide the information noted below to show how the new device is both similar to and different from the legally marketed device. Side by side comparisons, whenever possible are desirable (see Attachment 2). This information may be identical to that provided under Part D and the applicant may wish to combine some or all of Parts D and E information. Indicate how the differences may affect safety and effectiveness.

1. Provide labeling (labels, instructions for use, promotional material) for the legally marketed device(s) to which substantial equivalence is claimed. To

facilitate comparison, also include clear representations of the legally marketed device(s), unless the labeling has ample information.

2. Compare and contrast the intended use(s) for the new device to the predicate device(s).

3. Compare materials used to fabricate tissue or fluid contacting components. The precise materials of the tissue or fluid contacting components of the new device, and if possible, the predicate device(s) should be identified to the extent possible.

4. Compare the operational principles including mode of action.

5. Compare physical, operational, and biological specifications.

6. If applicable, compare results from bench testing (see F.).

F. Performance Data Supporting Substantial Equivalence

Provide the protocols and results of the tests indicated below. If the stated test is taken from a standard that specifically addresses the performance criterion, then the applicant should reference the standard and certify that the device will meet the criterion. Data need not be submitted in this instance.

The studies should be well-designed to meet the stated objectives. This will include rigorous attention to: statistical elements (hypotheses, test statistics, analyses, sample size and sampling, power, etc.), inclusion/exclusion criteria, controls, minimization of bias, test parameters (endpoints), follow-up, evaluation criteria, etc. Some of the above points may overlap. Ample reference material exists on study design and methods upon which the applicant may rely (e.g., biocompatibility).

1. Bench Data

   a. The accuracy of the device must be characterized. Devices which utilize standard type electrical transducer designs (e.g., standard thermocouple or thermistor) may not require testing. Devices which utilize other types of transducer designs (e.g., optical) or unique designs should have data showing the accuracy of device over the entire temperature range specified for the device. The effects of air currents, over the entire useful temperature range specified, on accuracy should also be provided.

   b. The precision and repeatability of the device over the temperature range specified for the device should be characterized as indicated above. The effects of air currents, over the entire useful temperature range specified, on precision and repeatability should also be provided.

2. Biocompatibility Data

   For all body tissue or fluid contacting materials certify that the identical materials have been used in other legally marketed devices under the same use conditions, or provide documentation attesting to the biocompatibility of the component materials in the finished product according to the 1987 Tripartite Biocompatibility Guidance for Medical Devices and 1992 draft ISO 194 standard (Biological testing of medical and dental materials and devices). With regard to metals, the applicant may simply identify device components made of an ASTM grade of metal that ASTM certifies is biocompatible, e.g., ASTM 316 stainless steel.

   Biocompatibility test data may be required for colors that are not listed in FDA regulations or are not used in other legally marketed devices for a similar intended use.

3. Comparative Claims

Additional data may be needed to support comparative claims.

4. Unique Designs

Additional data may be needed to support designs that are significantly different from typical designs.

G. Software

The sponsor must indicate the level of concern (see p.16 of the document indicated below) for electronic thermometers which are software controlled and provide appropriate software information according to the "Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review."

H. Sterilization Information

See Attachment 1

I. SMDA Information

Summary or Statement of Safety and Effectiveness

All persons submitting a 510(k) must include either a summary of safety and effectiveness information in the 510(k) upon which an equivalence determination could be based OR the statement "safety and effectiveness information about the [device name] will be made available to any interested person upon request." Safety and effectiveness information refers to adverse safety and effectiveness information, descriptive information about the new and predicate devices, and performance/clinical testing information.

If the summary option is selected, it should be included as a separate attachment and identified as the Summary of

Safety and Effectiveness for [device name].

If the statement option is selected, do not include the word "summary" in the statement.

The content and format of this information is specified in 57FR No. 82, Tuesday, April 28, 1992, page 18062.

J. Sample

Provide a sample of the device, if possible.

IV. COMMENTS

Address any comments regarding this guidance to:

Chief, General Hospital Devices Branch
HFZ-412
1390 Piccard Drive
Rockville, MD 20850-4308

Attachments

ATTACHMENT 1
STERILITY INFORMATION

For a device sold sterile, provide the following information as detailed in the ODE Blue Book Memorandum #K90-1.

1. Sterilization method that will be used.

2. A description of the method that will be used to validate the sterilization cycle, but not the validation data itself. Reference to a standard method (e.g., AAMI Radiation Standard) usually is sufficient.

3. The sterility assurance level (SAL) for the device which the firm intends to meet. An SAL of 10-6 is required for devices which contact normally sterile

areas of the body.

4. A description of the packaging to maintain the device's sterility (this is not to include packaging integrity testing data).

5. If sterilization involves EtO, the maximum levels of residues of ethylene oxide, ethylene chlorohydrin, and ethylene glycol which remain on the device. The levels should be consistent with the draft Federal Register Notice on EtO limits.1

6. Whether the product is "pyrogen free" and an identification of the method used to make that determination.2

7. The radiation dose, if radiation sterilization will be used, and if it has been determined. Otherwise, amend the 510(k) file at FDA when the dose has been determined.

References

1. FDA Proposed Rule, 43 FR 27482 (June 23, 1978), Maximum Residue Limits for Ethylene Oxide, Ethylene Chlorohydrin, and Ethylene Glycol.

2. FDA Guidelines on Validation of the Limulus Amebocyte Lysate (LAL) Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices.

## ATTACHMENT 2
## EXAMPLE OF SIDE BY SIDE COMPARISON TABLE

| ELEMENT OF COMPARISON | SUBJECT DEVICE | CLAIMED SE DEVICE #1 | (CLAIMED SE DEVICE (#2) |
|---|---|---|---|
| thermometer type | | | |

| | | | |
|---|---|---|---|
| intended use(s) | | | |
| labeling | | | |
| components | | | |
| sensor | | | |
| signal processing and display | | | |
| power requirements | | | |
| materials | | | |
| temperature range | | | |
| ambient temperature environment | | | |
| accuracy | | | |
| precision and repeatability | | | |
| response time | | | |
| other capabilities | | | |

SE=Substantially equivalent

The applicant may reference relevant standards in theTable .

ATTACHMENT 3 CLINICAL ELECTRONIC THERMOMETER REVIEW CHECKLIST

510(k)#:_____ Sponsor:_____ Date:_____ Reviewer:_____

ELEMENT ADEQUATE COMMENTS (e.g., N/A, page #, 30ml, YES NO 18g, PVC, EtO, $10^{-6}$, ¾ ")

Cover Letter

- trade name
- common name
- classification name
- establishment reg. #
- procode(s)
- purpose of submission
- previous files referenced

- statement that device is similar to and/or different from other products

Labeling specifications

- temperature range
- acccuracy
- precision
- ambient temperature environment
- instructions
  - type of temperature measurements
  - directions for use and interpretation of devce output
  - directions for reuse (cleaning/disinfection)
  - maintenance/recalibration instructions

Description of Device

  - type
  - basic description
  - photograph/drawing

Intended Use(s)

  - clear statement

- type of measurement(s)
- any other specific use

Physical Specifications

- component/component groups
- sensor/transducer
- signal processing and display
- power requirements
- materials

Operational Specifications

- temperature range
- accuracy
- precision and repeatability
- ambient temperature environment
- algorithms
- response time
- other capabilities

Biological Specifications

- biocompatibility require-ments for all fluid/tissue contact components and materials

Descriptive Comparison to Legally Marketed Device

- identified appropriate legally marketed device(s)
- labeling
- description
- intended use(s)
- materials
- mode of operation
- physical specifications
- operational specifications
- biological specifications
- side by side comparison
- discussion of how differences may affect safety and effectiveness

  Performance Data Supporting Equivalence
  - bench data

    accuracy

    precision and repeatability
- iocompatibility
- comparative claims
- unique designs

  Sterilization Information
  - method

- validation method
- SAL
- packaging description
- EtO residuals
- pyrogen free method
- radiation dose

SMDA Information

- summary
- statement

Sample

- provided

ADDITIONAL REMARKS:

**More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)**

**Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)**

**Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)**

**Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)**

**Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)**

**Office of Device Evaluation Final Guidance 2010 - 2016**
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)**

**Office of Device Evaluation Final Guidance 1998 - 2009**
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)**

**Office of Device Evaluation Final Guidance 1976 - 1997**
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)**

**Office of In Vitro Diagnostics and Radiological Health Final Guidance**
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)**

**Office of Surveillance and Biometrics Final Guidance**
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)**

**Office of Science and Engineering Laboratories Final Guidance**
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)**

**Draft Guidance**
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)**

**Radiation-Emitting Products Guidance**
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)**

**Withdrawn Guidance**
**(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)**