Guidance on the Content of Premarket Notification [510(K)] Submissions for Hypodermic Single Lumen Needles (Text Only)

April 1993

GUIDANCE ON THE CONTENT OF PREMARKET NOTIFICATION [510(K)] SUBMISSIONS FOR HYPODERMIC SINGLE LUMEN NEEDLES

I. INTRODUCTORY INFORMATION

A. Scope

This document establishes the 510(k) review requirements for hypodermic single lumen needles.

B. Purpose

This guidance is intended to:

1. assist persons (manufacturers, distributors, or importers) in organizing premarket notifications for hypodermic single lumen needles;

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 hypodermic single lumen needles.

C. Definitions

1. Hypodermic Single Lumen Needle: described in FDA regulation, 880.5570, as "a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set."

2. Nozzle: the portion of the barrel of the syringe to which a needle is attached. The types are as follows:

   Luer-lock: secures the needle onto the syringe by locking the needle hub onto the nozzle. The luer-lock makes a stable connection between the syringe and needle.

   Slip Tip: secures the needle with only a

compression fitting of the needle hub to the syringe nozzle.

Eccentric: provides a connection that is almost flush with the side of the barrel.

3. 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 needles may include single use only, disposable, and home use.

4. Abbreviations:
AAMI - Association for the Advancement of Medical Instrumentation
ASTM - American Society for Testing and Materials
CBER - Center for Biologics Evaluation and Research
CDER - Center for Drug Evaluation and Research
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
ISO - International Organization for Standardization
OCS - Office of Compliance and Surveillance
ODE - Office of Device Evaluation
SMDA - Safe Medical Devices Act of 1990

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 HYPODERMIC SINGLE LUMEN NEEDLE

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 needle's trade or proprietary name.

2. Common Name: Hypodermic Needle, etc.

3. Classification name: Hypodermic Single Lumen Needle

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

5. Class: II
Panel: 80
Procode: FMI - Hypodermic Single Lumen Needle

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 needle should include, if applicable:

   a. the identity of the device (gauge and length) and quantity;

   b. the statements "sterile, single use only, nonpyrogenic, nontoxic";

   c. the prescription statement under 801.109(b)(1);

C. Standards

Listed are some, but not all, of the standards relating to needles:

1. ISO 7864, Sterile Hypodermic Needles for Single Use;

2. ISO 594, Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment;

3. ISO 9626, Stainless Steel Needle Tubing for Manufacture of Medical Devices;

4. ISO 6009, Hypodermic Needles for Single Use - Colour Coding for Identification;

5. ASTM for stainless steel tubing testing.

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, please refer to the labeling.

2. Provide a clear description of the intended use(s) of the device.

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

   a. Physical Specifications

   (1) Needle: length, gauge, and configuration of the tip.

   (2) Cover: dimensions and color.

b. Mechanical Specifications

(1) Needle Cover: strength.

(2) Hub/needle: bond strength.

c. Biological Specifications

According to the draft ISO 194 Biocompatibility Standard, needles are categorized as Externally Communicating, Circulating Blood, Limited Exposure. The Tripartite Biocompatibility Guidance has a related categorization.

4. Provide a complete listing of all materials (chemical formulations), particularly those with fluid or body contact, used in fabricating the needle, hub, and needle cover.

Identify all colors (ink, dyes, markings, radiopaque materials, etc.) used in manufacturing the device.

E. Descriptive Comparison to a Legally Marketed Device

Identify a legally marketed needle to which substantial equivalence is claimed. If possible, identify the 510(k) number(s). More than one needle 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 1). This information may be identical to that provided under Part C and the applicant may wish to combine some or all of Parts C and D information. Indicate how any 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 for the new device to the predicate device(s).

3. Compare all materials used to fabricate the devices. The precise materials of the new device, and if

possible, the predicate device(s) should be identified to the extent possible.

4. Compare physical, mechanical, and biological specifications.

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. Biocompatibility

Certify that the identical materials have been used in other legally marketed devices used under the same use conditions, or provide data documenting 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). The test category of needles in the ISO standard are specified in Section D.3.(c) above. With regard to metals, if the applicant certifies that a component metal meets an ASTM standard where biocompatibility is indicated, e.g., ASTM 316 stainless steel, the certification will suffice for documentation purposes.

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.

2. Comparative Claims

Additional data may be needed to support comparative

claims.

3. Unique Designs

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

G. Sterilization Information

See Attachment 2

H. SMDA Information

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 a statement that 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 on a separate page 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.

I. Sample

Provide a sample, if possible.

J. Anti-needlestick Requirements

If the hypodermic single lumen needle incorporates an anti-needlestick mechanism, the applicant must completely describe the mechanism, demonstrate the equivalence of the mechanism, and substantiate all labeling claims associated with the anti-needlestick feature.

CDRH is currently writing a guidance document on the content of 510(k)s for devices incorporating antistick features and for stand-alone antistick devices. This document will be available from DSMA when finalized.

III. PREMARKET NOTIFICATIONS FOR KITS

1. See Attachment 3 for required information.

2. The following kit components require further evaluation by FDA and/or require language in an equivalence letter noting special requirements or limitations for these components:

Sutures
Dressings
Medical Gloves
Drugs
Biologics

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
EXAMPLE OF SIDE BY SIDE COMPARISON TABLE

ELEMENT OF COMPARISON	SUBJECT DEVICE	CLAIMED SE DEVICE #1	(CLAIMED SE DEVICE #2)
intended use(s)			
length			
gauge			
tip configuration			
cover dimensions			

cover color			
cover strength			
hub/needle bond strength			
biocompatibility			
materials			
labeling			
other			

SE=substantially equivalent The applicant may reference relevant standards in the Table. ATTACHMENT 2 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 Chlorohydin, 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 3 KIT INFORMATION The applicant must provide the following for a kit, i.e., a package consisting of at least one medical device and additional devices, drugs, or biologics as other components. 1. Include a complete and specific listing of all components of the kit(s). 2. Certifications: (a) I certify that the medical device components of my kit listed on page(s) [SUBMITTER PROVIDE PAGE NUMBERS] are either (1) legally marketed preamendments devices, (2) exempt from premarket notification (consistent with the exemption criteria described in the classification regulations and the limitations of exemptions from Section 510(k) of the act (e.g., 21 CFR 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 intended (i.e., not claiming or causing a new use for the component(s)). (b) I further certify that I purchase the device components in finished form, i.e., they are packaged, labeled, etc., consistent with their preamendments, exemption, or premarket notification criteria and status. All purchased drug or biologic components are also packaged and labeled consistent with their approval or licensing. If you cannot make certification statement (a) for each device component of your kit, you must itemize the components without preamendments, exemption, or premarket notification status. You must also supply adequate information so that FDA can evaluate the equivalence of these components of your kit. This information may be the same information needed for a separate 510(k) for each component. If you cannot make certification statement (b), then identify the components purchased in unfinished form, e.g., packaged in bulk (not final packaged and labeled in separate units). 3. Clearly identify in the list of kit components any that are drugs and biologics. For example, state next to the item that it is a drug or a biologic. 4. Describe how the kit is assembled and processed into finished form for purchase (e.g., the components are taken out of the finished product or bulk packaging, component X is individually sterilized, all the components are then placed on a tray, the kit is wrapped, but not sterilized prior to shipment). If there is any repackaging or reprocessing of a separate component, then you must provide details on the repackaging or processing and an analysis of the effect on the component. This may require testing. For

example, for (re)sterilized devices conduct a validation study and provide data in accordance with the ODE Sterility Blue Book Memorandum. The processing of the final kit is also important. You must evaluate whether the final processing for the kit as a whole affects the safety or effectiveness of any of the kit components. 5. The 510(k) should include all labels and labeling for the kit. A kit label alone may suffice for all components only if the label consolidates the required information typically found in labeling for each individual kit component when sold separately in final form. A component may require specific labeling, such as a package insert, when adequate directions for use (precautions, warnings, etc.) are required. It is important to examine the labeling for the individual components sold separately versus the labeling provided for the kit. Verify that the labeling is adequate or enclose additional labeling in the kit, as needed. 6. The items above identify labeling and processing issues which may affect the regulatory status, or safety and effectiveness of the kit. If you are aware of any other factor which may impact upon the status of your kit, then please bring it to our attention so that we may consider it in our evaluation. ATTACHMENT 4 HYPODERMIC SINGLE LUMEN NEEDLE REVIEW CHECKLIST 510(k)#: _____ Sponsor: _____ Date: _____ Reviewer: _____ ELEMENTADEQUATE 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
- purpose of submission
- previous files referenced
- statement that device is

  similar to and/or different

  from other products

Labeling

- identifies device

  gauge
  length
  quantity

- statements

sterile
single use only
nonpyrogenic
nontoxic
Rx

Description of Device

- basic description
- photograph/drawing

Intended Use(s)

- clear statement

Physical Specifications

- length
- gauge
- tip configuration

Mechanical Specifications

- cover strength
- hub/needle bond strength

Biological Specifications

- biocompatibility require-
  ments for all components
  and materials

Materials Identification

- needle
- cover
- hub
- any colors used in mfg.

Descriptive Comparison to Legally Marketed Device

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

Performance Data Supporting Equivalence

- biocompatibility
- comparative claim(s)
- unique design

Sterilization Information

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

SMDA Information

- summary
- statement

Sample

- provided

Kit Information

- list of components
- certification statements
- any drugs and/or biologics
- any sutures, dressings, gloves
- description of assembly
  and processing
- kit label/labeling

Antistick Feature If yes, see additional review

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)