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**GUIDANCE ON PREMARKET NOTIFICATION [510(K)]
SUBMISSION FOR SHORT-TERM AND
LONG-TERM INTRAVASCULAR CATHETERS**

**Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of General and Restorative Devices
General Hospital Branch**

03/16/95

PREFACE

Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters reflects a perceived need to address complications associated with this device. Manufacturing technology and clinical expertise have evolved such that commercially available catheters (and their associated labeling) may no longer adequately reflect the current expectation for safe and effective application.

Changes in catheter materials, labeling directions for modification of the device by the practitioner, applications that are clinically questionable, and the relatively high number of product notification submissions, have placed a heavy burden on the Food and Drug Administration to provide appropriate and timely evaluation of the applications.

The accompanying guidance document reflects the need to upgrade the requirements imposed on industry to provide safe and effective venous catheters for clinical use.

This draft document is provided to you (the affected industry), not only as guidance for 510(k) submission, but with an expectation that you will offer constructive criticism where deemed appropriate, so the guidance document may be improved from time to time. Please provide comments to the address given below, or call the General Hospital Branch at 301-594-1287:

Food and Drug Administration
Center for Devices & Radiological Health
Office of Device Evaluation (HFZ-410)
9200 Corporate Blvd.
Rockville, Maryland 20850

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GUIDANCE ON PREMARKET NOTIFICATION [510(K)] SUBMISSION
FOR SHORT-TERM AND LONG-TERM INTRAVASCULAR
CATHETERS

I. INTRODUCTORY INFORMATION

A. Scope

This document establishes the Premarket Notification [510(k)] review requirements for short and long-term intravascular catheters. Examples of devices within these generic types include: central venous catheters (CVCs), peripherally inserted venous catheters, peripherally inserted central catheters (PICCs), intravenous catheters (IV-Caths.), scalp vein catheters, umbilical vein catheters, etc.

Exclusions

This guidance does not address catheters used solely for diagnostic intended uses or catheters that are intended for interactive cardiovascular therapeutic purposes (e.g., percutaneous transluminal coronary artery [PTCA] catheters).

B. Purpose

This guidance is intended to:

1. assist persons (manufacturers, distributors, or importers) in organizing premarket notifications for intravascular catheters;
2. achieve consistency in meeting requirements and in the presentation of information and
3. guide FDA review staff in conducting and documenting the review of premarket notifications.

C. Definitions

Central Vein - The vena cava (superior or inferior).

Central Venous Catheter (CVC) - a tubular device, catheter, or cannula, placed within a vein and whose distal end is intended to be located within the vena cava (inferior or superior).

Dilator - a semi rigid tubular device used to dilate the puncture hole in a vessel through which a catheter, or cannula, is intended to be placed.

Distal End - The patient-end of a vascular catheter. With CVCs, the end intended for location within the vena cava.

Finder or Locator Needle - A hypodermic needle used as a probe to locate the appropriate vessel for catheter insertion. Usually of smaller gauge than the "Placement Needle."

Guidewire - (Also wire guide) A wire used to facilitate placement of a catheter within the vasculature. (Also, used to enhance radiographic contrast when imaging a placed CVC).

Intravascular Catheter - described in the FDA regulation, 21 CFR 880.5200, as "a device that consists of a slender tube and any necessary connecting fittings and that is inserted into the patient's vascular system for short-term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. The device may be constructed of metal, rubber, plastic, or a combination of these materials."

This guidance document also includes catheters intended for long-term use (30 days or more). However, at this time FDA has not specifically classified such devices intended for more than 30 day placement. These devices are "unclassified."

Intended Use - the clinical application(s) for which the device is intended, includes 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), or it may be implicit in the design of the device.

Introducer - a semi rigid conduit or guide placed through the skin and into a vessel to facilitate the passage of a catheter or cannula into that vessel.

Peripheral Catheter - A vascular catheter or cannula whose indwelling vascular component is limited to a peripheral vessel. (Not within the vena cava).

Peripherally Inserted Central Catheter (PICC) - A CVC with placement access via a peripheral vein.

Peripheral Placement - Used to indicate that the catheter at issue is not a CVC, but its distal end is intended to be located in a peripheral vein.

Placement Needle - A hypodermic needle which is introduced into a blood vessel and through which a catheter, guidewire, or stylet is passed in order to gain catheter-access to that vessel.

Proximal End - The user-access end of a vascular catheter. With CVCs, the end furthest from the vena cava.

Stylet - See "Guidewire."

D. General Principles Regarding Presentation of Data

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

2. 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.

It is suggested that data used for the 510(k) submission be kept on file in an organized format to expedite supplying FDA information or analysis if required. Errors in data that are identified by the applicant after submission to FDA should be brought to FDA's immediate attention.

3. 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.

4. Published Literature: Published methods or data referenced in study reports should be appended to the study report. Reprints of other referenced published reports or data should be appended to the section in which they are referenced. All referenced reports and data should be summarized including an explanation of how it relates to the current submission. Reference citations should be complete (e.g., title, author, volume, page(s), year).
5. 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.
6. 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.
7. Abbreviations: Standard abbreviations acceptable to a significant peer reviewed journal should be used where appropriate. All other abbreviations should be identified at the beginning of each section in which they are used or in footnotes to tables and graphs.

AAMI Association for the Advancement of Medical Instrumentation
ANDA Abbreviated New Drug Application (FDA)
ANSI American National Standards Institute
ASTM American Society for Testing and Materials
CDC Centers for Disease Control and Prevention
CBER Center for Biologics Evaluation and Research (FDA)
CDER Center for Drug Evaluation and Research (FDA)
CDRH Center for Devices and Radiological Health (FDA)
CFR Code of Federal Regulations
CVC Central Venous Catheter
DSMA Division of Small Manufacturers Assistance (FDA)

FDA	Food and Drug Administration
FR	Federal Register
HIMA	Health Industry Manufacturers Association
ISO	International Organization for Standardization
IJ	Internal Jugular (vein)
IV	Intravenous
NDA	New Drug Application (FDA)
OCS	Office of Compliance and Surveillance (FDA)
ODE	Office of Device Evaluation (FDA)
PICC	Peripherally Inserted Central Catheter
PTCA	Percutaneous Transluminal Coronary Angioplasty
SMDA	Safe Medical Devices Act of 1990
SVC	Superior Vena Cava
TPN	Total Parenteral Nutrition

E. Relevant Documents:

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

- Tripartite Biocompatibility Guidance for Medical Devices (Sept 1986)
- ODE Blue Book Memorandum #K90-1: 510(k) Sterility Review Guidance
- Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices with Sharps Injury Prevention Features (Feb. 1994)

II. CONTENT AND ORGANIZATION OF INFORMATION IN A 510(k):

A. Cover Letter

The submission shall have a cover letter providing the following information described in 21 CFR 807.87 (Information required in a premarket notification submission):

1. Date of submission.
2. The device's trade or proprietary name.
3. The device's common or usual name: Percutaneous intravascular catheter, intravenous catheter (IV catheter), central venous catheter (CVC), peripherally inserted central catheter (PICC), subclavian vein catheter, internal jugular vein catheter (IJ-Cath.), peripheral venous catheter, scalp vein catheter, etc.
4. The establishment registration number, if applicable, of the sponsor, owner or operator submitting the premarket notification.
5. The firm's contact person for FDA communications, with address, telephone and fax numbers. (U.S. contact if available).

6. The device's classification name:
Short-term catheters (less than 30 days) - Percutaneous Intravascular catheter.
Long-term catheters (30 days or more) - unclassified.
7. The FDA device Class:
 - Class II for short-term Intravascular Catheters (less than 30 days).
 - Unclassified for long-term (more than 30 days) Percutaneous Intravascular Catheters.
8. The FDA Panel Number: 80
9. Product Code (PROCEDURE):
FOZ - Intravascular Catheter
LJS - Long-term Intravascular Catheter
10. A statement explaining the purpose of the submission (e.g., new device, significant modification of device previously found equivalent, new intended use, new 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.
11. A brief statement indicating that the device is similar to and/or different from other products of comparable type in commercial distribution.

B. Labels and Labelling

1. The submission should contain draft labels, labelling, 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 includes professional or patient package inserts, and any other information that may accompany 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 therefore concentrate on the following:
 - Subpart A, Sections 801.4 and 801.5, related to intended uses and adequate directions for use.
 - Subpart B, Sections 801.109 and 801.116, related to prescription devices and commonly known directions.
Other labeling issues are deferred for review to CDRH/Office of Compliance, Labeling Compliance Branch.
3. Device labeling for the intravascular catheter shall:
 - a. Include the device description and specifications, to include useful length, outer diameter (OD) and inner diameter (ID), both dry and hydrated (when

hydrophilic materials are used. See following note *).

(*Note: This applies to devices in a hydrated steady state, wherein hydration may affect clinical application, e.g.s., produces a change in gauge size, flow rate, or useful length).

- b. Include the volume required to prime (lumen volume) the catheter. (Caution shall be provided where small infant use is anticipated and priming or flushing the catheter is anticipated).
- c. Include a depiction or description of the distal end configuration.
- d. Give the distance between depth markings when depth markings are used. They shall be indicated and expressed in cm from the distal end.
- e. Specify indication(s) for use: such as, pressure monitoring, blood sampling, administration of fluids (eg: TPN, chemotherapeutic agents, antibiotics, etc.).
- f. Catheters with components that are susceptible to magnetic influence shall be labelled "Contraindicated Where Magnetic Resonance Imaging (MRI) is anticipated."
- g. Specify the recommended vascular access for placement, eg: by way of the antecubital peripheral veins, left subclavian vein, internal jugular vein, umbilical vein, etc.
- h. Specify the final intended anatomic location(s) for placement of the distal catheter tip and provide instructions for assuring tip location through radiographic means.

NOTE: When catheter application is intended for other than vena caval tip placement, the practitioner shall be made aware about the use of infusates or other materials not recommended for infusion into smaller vessels. This includes such materials as cytolytic and caustic agents, hypo- hyper-ostomic materials, etc.

- i. Provide instructions for pediatric and/or neonatal use when such application is intended, or anticipated, or if intended for a specific patient population.

NOTE: Catheters that are 3Fr [1mm, or 0.039 in.] or less in diameter, are assumed to be applicable for pediatric patients and require additional instructions relative to pediatric use. In the absence of such instructions, the device label must include the statement, "Not intended for pediatric or neonatal use."

- j. Where specific drugs are indicated for administration in the device labeling, such drugs must be FDA-approved for the indicated route of administration.
- k. Present warnings and cautions in bold face or italicized print. They should be obvious and clearly displayed.

- l. Indicate radiographic detectibility of the catheter. Where radiographic markers are used, clearly indicate their location in the description and/or illustration of the device.
- m. Where device modification is offered to the practitioner (such as distal catheter tip trimming ¹), a quality assurance mechanism must be provided such that the modification will not result in a product that alters the safety or efficacy of the device as presented by the manufacturer to the FDA as a final product. (This may require additional test data).
- n. Provide statements for sterility, non-pyrogenicity, single-use only, prescription, etc., as appropriate.
- o. Provide a statement addressing the maximum length of time the catheter may remain in situ and/or a reference to the CDC (Centers for Disease Control and Prevention) Guidelines. Catheters that are peripheral (see definitions), should not state, or imply, that such catheters may remain in situ for periods in excess of the CDC Guidelines; (i.e., 72 hrs.), unless supporting evidence is offered.
(Refer to Section F for data requirements to support extended times).
- p. Claims for antimicrobial or antithrombotic features must be supported by appropriate data. (See Section F for data requirements). Such components must be specified as to the purpose of the component. (For antimicrobials, state the spectrum of activity).
- q. Provide a statement that alerts the practitioner to apply a catheter maintenance protocol and catheter insertion site maintenance protocol consistent with accepted standards of practice.
- r. Provide an expiration date, as appropriate, in consideration of the degradation of coatings and/or impregnated additives such as, lubricants, antithrombotics, antimicrobials, etc.
- s. Give any specific drug or biologic use(s).
- t. If any material in the fluid path includes the plasticizer, diethylhexylphthalate (DEHP), then the labeling shall state, "Contains DEHP."
- u. Provide instructions for infusion/blood withdrawal, where applicable.
- v. Provide a statement that alerts the practitioner to the potential hazard of catheter occlusion. Recommend that the practitioner adhere to an appropriate clearing procedure.
- w. Provide instructions addressing catheter migration (forward, towards the heart and backward, toward the access site, or tributary veins).

¹ Instructions for catheter trimming shall provide a reminder to maintain aseptic technique, cut the catheter squarely (no points), and in such a manner that produces a clean, smooth surface.

- x. Give the size (diameter) of compatible guidewire. Note if the catheter is not suitable for use with a guidewire or certain type of guidewire.
- y. Recommend the application of "Universal Precautions."

C. Standards

Listed are some recommended, voluntary standards relating to intravascular catheters:

1. BS 4843:1987 British Standard Specification for Sterile Intravascular Cannula Units for Single Use
2. BS 7174:1990 British Standard Sterile Intravascular Catheters and Ancillary Devices for Single Use
3. ISO 10555 (1994 draft) International Organization for Standards - Sterile, single use intravascular catheters (Part 1: "General Requirements" and Part 3: "Central Venous Catheters").

Other appropriate or relevant industry or regulatory standards which the device meets/should meet, should be referenced including the year of the standards publication.

The applicant may certify that the device meets a standard. The applicant then is obliged to meet the standard and maintain documentation of testing 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. State the type(s) of catheters. 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 may be needed). If the labeling already includes sufficient illustrations of the device, please refer to the labeling. (a sample of the device may be necessary, or helpful in expediting the review process).
2. Provide a clear statement of the indication(s) for use of the device.
3. Include clear, labeled illustration(s) of the proximal and distal ends (including valves where present) of the catheter.
4. Provide the specifications for the device. The applicant may refer to relevant standards.

a. Physical Specifications

Provide the following:

- (1) dimensions (ID, OD, effective length) dry, and hydrated for hydrophilic materials (See note at II,B,3a).
- (2) number and shape of lumen(s);
- (3) flow rate for each lumen (dry/hydrated) in milliliters/min., according to ISO 10555 (1994 draft), or equivalent flow rate test.
- (4) proximal and distal end configurations: shape, location and diameter of outlets and side ports. (Indicate Luer connector(s), injection site(s), etc.)

b. Mechanical Specifications dry, and hydrated for hydrophilic materials. (See note II,B,3a).

Provide the following:

- (1) tensile strength of catheter body;
- (2) tensile strength of catheter body to hub attachment;
- (3) catheter stiffness;
- (4) catheter tip (distal) attachment strength;
- (5) catheter elongation;
- (6) leakage at hub;
- (7) catheter burst pressure (positive internal pressure);
- (8) catheter collapse (negative internal pressure);
- (9) catheter flexural fatigue tolerance.

c. Biological Specifications

According to the draft ISO 194 Biocompatibility Standard, catheters are categorized as Externally Communicating Devices, Circulating Blood, Limited (short-term IV catheters), or Prolonged/Permanent Exposure (e.g., central venous catheters). The Tripartite Biocompatibility Guidance has a related categorization.

d. Chemical Specifications

Provide the following:

- (1) composition of any antimicrobial or antithrombotic ingredient and method of coating, impregnating, or formulation of the catheter.
- (2) Indicate the stability requirements for any chemical applied on or incorporated into the device to enhance its clinical performance (e.g., lubricant, antithrombotic, antimicrobial).
- (3) State the compatibility conditions for the device with any specific drug or biologic referenced in the device labeling.
- (4) Provide a complete listing of all device materials. Identify all colors (ink, dyes, markings, radiopaque materials, etc.) used in the device.

E. Descriptive Comparison to a Legally Marketed Device

Identify a legally marketed catheter to which substantial equivalence is claimed. If possible, identify the 510(k) number(s). More than one catheter 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 the differences may affect safety and effectiveness.

1. Compare 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 photographs, or other representations of the legally marketed device(s), unless the labeling has ample information.
2. Compare and contrast the intended use and instructions for use for the new device and the predicate. Include the intended anatomical placement location for the distal catheter tip.

(Note: Predicate device labeling may be inadequate, by today's knowledge of safety and effectiveness, to be used as the guideline for clearly presenting the intended use of the proposed device.)

3. Compare all materials used to fabricate the specified or major components. The precise materials of the new device, and if possible, the predicate should be identified to the extent possible.
4. Compare physical, mechanical, etc., 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.

Samples for testing should represent the finished product; i.e., after sterilization, or exposure to other procedures that can affect chemical makeup or material properties.

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**

- a. Certify that the identical materials have been used in other legally marketed devices used under the same use conditions, or
- b. Provide the biocompatibility of the component materials in the finished product according to the 1987 Tripartite Biocompatibility Guidance for Medical Devices, or provide certification that the identical materials are used in another legally marketed predicate device under comparable conditions of use.

The test category of catheters in the ISO standard are specified in Section II,D,c (above).

Note: 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 safety and effectiveness data may be needed to support comparative claims.

3. **Unique Design**

Additional data may be needed to support designs that are significantly different from typical designs, such as catheters designed for so-called "midline", or "midclavicular placement" (distal end location in axillary, or sub clavicular vein), or for device modification suggested in the labelling (eg. catheter trimming).

4. **Drug/Biologic and Device Compatibility**

Data demonstrating drug or biologic and material compatibility is required if a specific drug or biologic is referenced in the device labeling.

5. Performance of antimicrobial or antithrombotic-augmented catheters

Submissions for catheters with substances or components added to enhance clinical performance will require additional data to verify specifications and claims. The following must be provided on such devices after sterilization:

- a. such substances or components must be specified as to their purpose;
- b. stability data: testing for shelf life/expiration date including effect of storage and adverse shipping conditions (must be reflected in labeling);

(Note: Accelerated aging tests are acceptable in support of initial shelf-life expiration dates; however, real-time stability studies must be instituted prior to any finding of "substantial equivalence" to a legally marketed predicate device).
- c. in-vitro performance (e.g., Minimum Inhibitory Concentration, elution profile);
- d. in vitro test data to determine spectrum and degree of activity against all clinically important microorganisms, indicating the incidence of infection associated with the microorganism chosen;
- e. metabolism and excretion data for the antimicrobial/antithrombotic materials;
- f. an explanation of the rationale for the concentration of the antimicrobial/antithrombotic incorporated into the device to include any dose ranging information (e.g., effectiveness versus toxicity) and data to show that the material is not eluted in a concentration sufficient to have a pharmacological effect;
- g. for antimicrobials, randomized, controlled clinical study data demonstrating antimicrobial activity on the device during handling and placement, a clinically and/or statistically significant decrease in the rate of bacterial colonization on the device and infection in the area it is applied to, compared to a legally marketed predicate device, and data to support any additional claims;
- h. for antimicrobials, the complete protocol for the microbiology tests to allow for a full analysis and understanding of the data;
- i. demonstrate whether the antimicrobial/antithrombotic causes any changes in the device specifications;
- j. the spectrum of activity of the antimicrobial (must be reflected in the labeling);
- k. any additional contraindications, cautions, warnings, and adverse effects relevant to the antimicrobial/antithrombotic (must be reflected in the labeling);

- l. a statement in the labeling, if appropriate, that the principal site of action of the antimicrobial/antithrombotic agent is on the surface of the device;
- m. provide an exact identification of all device materials, including the exact formulation(s) of antimicrobial/antithrombotic components; a statement regarding any material differences from a legally marketed predicate device, and references, if possible, to a new drug application (NDA) or over the counter (OTC) drug monograph for the antimicrobial/antithrombotic agent(s) for the intended use. If it is not an NDA or OTC drug, then additional information may be required.

(Guidance for an NDA or OTC drug may be obtained from the Center for Drug Evaluation and Research at (301-443-4300)

If the materials are identical to a legally marketed predicate device and are identically processed and sterilized, then this should be explicitly stated.

- 6. Data supporting intended use of peripheral catheters beyond 72 hours.

G. Sterilization Information

See Attachment 2

H. 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 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 57 Federal Register No. 82, Tuesday, April 28, 1992, page 18062.

I. Sample

Provide a sample of the device, if possible. This can facilitate the evaluative process.

J. Anti-needlestick Requirements

If the catheter 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. Submission of a sample may expedite the review.

Note: CDRH has Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices with Sharps Injury Protection Features. This document is available from DSMA.

III. PREMARKET NOTIFICATION FOR KITS

1. See Attachment 3 for required information.
2. The following kit components require further evaluation by FDA and/or requires language in an equivalence letter noting special requirements or limitations for these devices:

Sutures
Dressings
Medical Gloves
Drugs
Biologics

IV. COMMENTS

Address any comments regarding this guidance to:

Chief, General Hospital Devices Branch
HFZ-412
9200 Corporate Blvd.
Rockville, MD 20850-4308

Attachments

03/16/95

**ATTACHMENT 1
EXAMPLE OF SIDE BY SIDE COMPARISON TABLE**

ELEMENT OF COMPARISON	SUBJECT DEVICE	CLAIMED SE DEVICE #1 510(k) No.	CLAIMED SE DEVICE #2 510(k) No.
catheter type			
intended use(s)			
mode of operation			
ID (dry/hydrated)			
OD (dry/hydrated)			
length (dry/hydrated)			
lumens (#, diam. and shape)			
distal end configuration			
intended anatomical location of distal end			
proximal end configuration			
composition of anti-microbial/antithrombotic			
water flow rate (ml/min) (dry/hydrated)			
Cath body tensile strength (dry/hydrated)			
Cath stiffness			
body to hub tensile strength			
tip attachment strength (dry/hydrated)			
Cath elongation			
leakage at hub (dry/hydrated)			
burst pressure (pos. and vacuum)			
Cath flexural fatigue tolerance			
biocompatibility			
chemical			
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 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 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 biologic as other components.

- 1. Include a complete and specific listing of all components of the Kit(s).**
- 2. Certifications:**
 - (a) Certify that the medical device components of the 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) Further certify that the device components are purchased 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 biologic. 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
CATHETER REVIEW CHECKLIST**

510(k)#: _____

Sponsor: _____

Date: _____

Reviewer: _____

ELEMENT

ADEQUATE
YES NO

COMMENTS (e.g., N/A, page #, 30ml, 18g, PVC, EtO, 10⁶, 3/4", pediatric use)

Cover Letter

- trade name YES NO _____
- common name YES NO _____
- classification name YES NO _____
- establishment reg. # YES NO _____
- procode(s) YES NO _____
- purpose of submission YES NO _____
- previous files referenced YES NO _____
- statement that device is similar to and/or different from other products YES NO _____
- firm's contact person YES NO _____

Labeling

- identifies device attribute YES NO _____
- statements YES NO _____
 - sterile YES NO _____
 - single use only YES NO _____
 - nonpyrogenic YES NO _____
 - nontoxic YES NO _____
 - R_x YES NO _____
- antithrombotic/antimicrobial YES NO _____
- specialized instructions YES NO _____
- cath trim QA instructions YES NO _____

<u>ELEMENT</u>	<u>ADEQUATE</u>		<u>COMMENTS</u> (e.g., N/A, page #, 30ml, 18g, PVC, EtO, 10 ⁻⁶ , 3/4", pediatric use)
	YES	NO	
• pediatric/neonatal use indication	<input type="checkbox"/>	<input type="checkbox"/>	_____
• MRI-Compatible	<input type="checkbox"/>	<input type="checkbox"/>	_____
• compatible guidewire size	<input type="checkbox"/>	<input type="checkbox"/>	_____
• universal precautions recommended	<input type="checkbox"/>	<input type="checkbox"/>	_____
<u>Description of Device</u>			
• type	<input type="checkbox"/>	<input type="checkbox"/>	_____
• basic description	<input type="checkbox"/>	<input type="checkbox"/>	_____
• photograph/drawing	<input type="checkbox"/>	<input type="checkbox"/>	_____
<u>Intended Use(s)</u>			
• clear statement	<input type="checkbox"/>	<input type="checkbox"/>	_____
• anatomical location of distal catheter tip	<input type="checkbox"/>	<input type="checkbox"/>	_____
• instructions for tip location assurance	<input type="checkbox"/>	<input type="checkbox"/>	_____
<u>Physical Specifications</u>			
• dimensions (dry/hydrated): I.D., O.D., Useful length	<input type="checkbox"/>	<input type="checkbox"/>	_____
• lumens (No., shape)	<input type="checkbox"/>	<input type="checkbox"/>	_____
• priming volume(s)	<input type="checkbox"/>	<input type="checkbox"/>	_____
• distal end configuration	<input type="checkbox"/>	<input type="checkbox"/>	_____
• proximal end configuration	<input type="checkbox"/>	<input type="checkbox"/>	_____
• antimicrobial/antithrombotic composition	<input type="checkbox"/>	<input type="checkbox"/>	_____
• flow rate (dry/hydrated)	<input type="checkbox"/>	<input type="checkbox"/>	_____
<u>Mechanical Specifications</u> (dry/hydrated):			
• cath body tensile strength	<input type="checkbox"/>	<input type="checkbox"/>	_____
• body to hub attachment strength	<input type="checkbox"/>	<input type="checkbox"/>	_____
• cath stiffness	<input type="checkbox"/>	<input type="checkbox"/>	_____

<u>ELEMENT</u>	<u>ADEQUATE</u>		<u>COMMENTS</u> (e.g., N/A, page #, 30ml, 18g, PVC, EtO, 10 ⁻⁶ , 3/4", pediatric use)
	YES	NO	
• tip attachment strength	<input type="checkbox"/>	<input type="checkbox"/>	_____
• cath/elongation	<input type="checkbox"/>	<input type="checkbox"/>	_____
• leakage at hub	<input type="checkbox"/>	<input type="checkbox"/>	_____
• burst pressure (pos/neg)	<input type="checkbox"/>	<input type="checkbox"/>	_____
• flexural fatigue tolerance	<input type="checkbox"/>	<input type="checkbox"/>	_____
<u>Materials Identification</u>			
• attribute	<input type="checkbox"/>	<input type="checkbox"/>	_____
• any colors used in mfg.	<input type="checkbox"/>	<input type="checkbox"/>	_____
• depth distance markers	<input type="checkbox"/>	<input type="checkbox"/>	_____
• radiographic detectibility	<input type="checkbox"/>	<input type="checkbox"/>	_____
<u>Biological Specifications</u>			
• biocompatibility requirements for all components and materials	<input type="checkbox"/>	<input type="checkbox"/>	_____
<u>Chemical Specifications</u>			
• stability requirements drug/biologic storage	<input type="checkbox"/>	<input type="checkbox"/>	_____
<u>Descriptive Comparison to Legally Marketed Device</u>			
• identified appropriate legally marketed device(s)	<input type="checkbox"/>	<input type="checkbox"/>	_____
• labeling	<input type="checkbox"/>	<input type="checkbox"/>	_____
• description	<input type="checkbox"/>	<input type="checkbox"/>	_____
• intended use(s)	<input type="checkbox"/>	<input type="checkbox"/>	_____
• materials	<input type="checkbox"/>	<input type="checkbox"/>	_____
• mode of operation	<input type="checkbox"/>	<input type="checkbox"/>	_____
• physical specifications	<input type="checkbox"/>	<input type="checkbox"/>	_____
• mechanical specifications	<input type="checkbox"/>	<input type="checkbox"/>	_____

<u>ELEMENT</u>	<u>ADEQUATE</u>		<u>COMMENTS</u> (e.g., N/A, page #, 30ml, 18g, PVC, EtO, 10 ⁻⁶ , 3/4", pediatric use)
	YES	NO	
• biological specifications	<input type="checkbox"/>	<input type="checkbox"/>	_____
• chemical specifications	<input type="checkbox"/>	<input type="checkbox"/>	_____
• side by side comparison	<input type="checkbox"/>	<input type="checkbox"/>	_____
• distal tip placement	<input type="checkbox"/>	<input type="checkbox"/>	_____
• discussion of how differences may affect safety and effectiveness	<input type="checkbox"/>	<input type="checkbox"/>	_____
<u>Performance Data Supporting Equivalence</u>			
• biocompatibility	<input type="checkbox"/>	<input type="checkbox"/>	_____
• comparative claim(s)	<input type="checkbox"/>	<input type="checkbox"/>	_____
• unique design	<input type="checkbox"/>	<input type="checkbox"/>	_____
• antimicrobial/antithrombotic	<input type="checkbox"/>	<input type="checkbox"/>	_____
<u>Sterilization Information</u>			
• method	<input type="checkbox"/>	<input type="checkbox"/>	_____
• validation method	<input type="checkbox"/>	<input type="checkbox"/>	_____
• SAL	<input type="checkbox"/>	<input type="checkbox"/>	_____
• packaging	<input type="checkbox"/>	<input type="checkbox"/>	_____
• EtO residuals	<input type="checkbox"/>	<input type="checkbox"/>	_____
• pyrogen free method	<input type="checkbox"/>	<input type="checkbox"/>	_____
• radiation dose	<input type="checkbox"/>	<input type="checkbox"/>	_____
<u>SMDA Information</u>			
• summary	<input type="checkbox"/>	<input type="checkbox"/>	_____
• statement	<input type="checkbox"/>	<input type="checkbox"/>	_____
<u>Sample</u>			
• provided	<input type="checkbox"/>	<input type="checkbox"/>	_____
<u>Kit Information</u>			
• list of components	<input type="checkbox"/>	<input type="checkbox"/>	_____
• certification statements	<input type="checkbox"/>	<input type="checkbox"/>	_____

ELEMENT

ADEQUATE
YES NO

COMMENTS (e.g., N/A, page #, 30ml,
18g, PVC, EtO, 10⁻⁶, 3/4", pediatric
use)

- | | | | |
|---|--------------------------|--------------------------|-------|
| • any drugs and/or biologics | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| • any sutures, dressings, gloves | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| • description of assembly
and processing | <input type="checkbox"/> | <input type="checkbox"/> | _____ |