Contains Nonbinding Recommendations

Guidance for Industry and FDA Staff

Intravascular Administration Sets Premarket Notification Submissions [510(k)]

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This document supersedes Guidance for Industry and FDA Reviewers on the Guidance on Premarket Notifications for Intravascular Administration Sets," issued April 15, 2005.

For questions regarding this document, please contact Mr. Anthony Watson at 240-276-3700

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Food and Drug Administration
Center for Devices and Radiological Health
General Hospital Devices Branch
Division of Dental, Infection Control, and General Hospital Devices
Office of Device Evaluation

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/ode/guidance/1189.html. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number (1189) to identify the guidance you are requesting.

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Guidance for Industry and FDA Staff

Intravascular Administration Sets Premarket Notification Submissions [510(k)]

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

FDA has developed this guidance document to assist industry in preparing premarket notification (510(k)s) submissions for intravascular (IV) administration sets and accessories. This revision of the document issued in 2005 updates the FDA-recognized standards and clarifies our recommendations for microbial ingress testing. IV administration sets and accessories include:

- extension sets
- IV stopcocks and manifolds
- in-line filters
- flow regulators
- fluid delivery tubing
- vial adapters
- IV transfer sets
- subcutaneous administration sets
- blood administration sets
- transfusion filters.

IV administration sets with or without needleless access devices or systems are also addressed in this guidance. A needleless system may be incorporated as an integral

component (e.g., a Y-site connector), or may be marketed separately as an accessory (e.g., attached to other devices by the user at the point of use.)

If your device contains a sharps injury prevention (safety) feature, we recommend that you consult the guidance entitled, **Supplementary Guidance on Premarket Notifications for Medical Devices with Sharps Injury Prevention Features**, http://www.fda.gov/cdrh/ode/guidance/934.html for information about simulated use testing of sharps injury prevention features.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe should be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the document "A Suggested Approach to Resolving Least Burdensome Issues." It is available on our Center's Web page at http://www.fda.gov/cdrh/modact/leastburdensome.html.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. Background

A manufacturer who intends to market a device of this generic type must conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the act), including the premarket notification requirements described in 21 CFR 807 Subpart E, and obtain a substantial equivalence determination from FDA prior to marketing the device. (See also 21 CFR 807.81 and 807.87.)

This guidance document identifies the classification regulation and product codes for hemodialysis blood tubing sets (refer to **Section 4. Scope**). Other sections of this guidance document provide additional information to manufacturers on addressing risks related to these devices in premarket notifications (510(k)s).

This document supplements other FDA documents regarding the specific content requirements of a premarket notification submission. You should also refer to 21 CFR

807.87, the guidance, **Format for Traditional and Abbreviated 510(k)s**,[1] and "Premarket Notification 510(k)**"** on CDRH Device Advice.[2]

Under "**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications**,"[3] a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once FDA has issued a guidance document addressing that device. Manufacturers considering certain modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), we recommend that you include a descriptive summary report of appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g). The descriptive summary report should explain how this guidance document was used during the device development and testing, briefly describe the methods or tests used, and include a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document and any other additional risks specific to your device. This section suggests information to fulfill some of the requirements of section 21 CFR 807.87 and identifies other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this guidance document.

Proposed Labeling

Proposed labeling must be sufficient to describe the device, its intended use, and the directions for its use. (21 CFR 807.87(e)) (Please refer to **Section 11. Labeling** for specific information that should be included in the labeling for devices of the type covered by this guidance document.)

[1] http://www.fda.gov/cdrh/ode/guidance/1567.html
[2] http://www.fda.gov/cdrh/devadvice/314.html
[3] http://www.fda.gov/cdrh/ode/parad510.html

Abbreviated 510(k) Summary Report[4]

In accordance with 21 CFR 807.87, your summary report should contain the following:

Description of the device and its intended use

Please describe the device and include an explanation of how the device functions and the specific physical and performance characteristics of the device. Refer to **Section 5. Device Description** for specific information to include in the device description for devices of the type covered by this guidance document. You should also submit an "indications for use" enclosure.[5]

Description of device design

You must include a brief description of the device design requirements. (21 CFR 807.87(f))

Identification of the risk analysis method

We recommend that you identify the risk analysis method(s) you used to assess the risk profile, in general, as well as the risk profile of the specific device's design and the results of this analysis. Please refer to **Section 6. Risks to Health** for the risks to health generally associated with the use of this device that FDA has identified.

Discussion of the device characteristics

We recommend that you discuss the device characteristics that address the risks identified in this guidance document and any additional risks identified in your risk analysis.

Description of the performance aspects

You should describe the nonclinical tests submitted, referenced, or relied on in your submission. See **Sections 7-10** of this guidance for specific performance aspects. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.[6] (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

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[4] This is not the report described in 21 CFR 807.92, which may be submitted to satisfy 21 CFR 807.87(h).

[5] Refer to http://www.fda.gov/cdrh/ode/indicate.html for the recommended format.

[6] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance

Reliance on standards

If you choose to rely on a recognized standard for any part of the device design or testing, you may include either a:

- statement that testing will be conducted and meet specified acceptance criteria before the device is marketed; or
- declaration of conformity to the standard.[7]

Because a declaration of conformity is based on results from testing, you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the act and the FDA guidance, **Use of Standards in Substantial Equivalence Determinations**.[8]

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. Under 21 CFR 807.87(l), you must submit any additional information that is necessary to reach a determination regarding substantial equivalence.

As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering certain modifications to their own cleared devices should consider submitting Special 510(k)s.

The following is a specific discussion of how you should apply this guidance document to a premarket notification submission for IV administration sets and accessories.

4. Scope

The scope of this document is limited to the device defined in 21 CFR 880.5440, class II, and assigned the product codes described in the table below.

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criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

7 See http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf

8 See http://www.fda.gov/cdrh/ode/guidance/1131.html

Procode	Common Name
FMG	IV Set Stopcock *(includes manifolds)*
FPA	Intravascular Administration Set *(includes needleless access devices/systems and blood flow regulator)*
BRZ	Blood Transfusion Set
FPB	Infusion Line (In-Line) Filter
CAK	Blood Transfusion Microfilter
FPK	Fluid Delivery Tubing
LHI	IV Fluid Transfer Set *(includes vial adapter)*

Pharmacy compounding systems (procode NEP) classified in the intravascular administration set identification are exempt from the premarket notification procedures, subject to the limitations in 21 CFR 880.9.

> **Section 880.5440 Intravascular Administration Set**
> An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.

IV administration sets administer fluids to a patient's vascular system by various means, gravity flow, via a pump, subcutaneously, or through implanted vascular ports. These IV sets may include Diethylhexylphthalate (DEHP) and non-DEHP PVC tubing, co-extruded tubing, calibrated burettes, filters, standard and needle free Y-injection sites (swabbable and non-swabbable), anti-siphon valves, and check valves to prevent retrograde fluid flow.

5. Device Description

We recommend that you identify your device by regulation and product code described in **Section 4. Scope,** and include the following information:

- indications for use
- design features; i.e., materials, configurations, size, safety features
- specifications and dimensions
- materials, including chemical formulation
- conformance with standards.

Side by side comparisons of the information described below, whenever possible, in tabular format are desirable. We recommend that you describe how any differences may affect the comparative safety and effectiveness of the new device.

Material Composition

We recommend that you provide a complete listing of all device materials (trade name and chemical formula) and identify any metallic components. Metallic components may affect the safety of the device in an MRI environment. We also recommend that you identify any polyvinylchloride (PVC) plasticizers, lubricants, bonding agents, or other additives (e.g., color additives, ink, dyes, markings, radiopaque materials) and provide their amounts.

It is helpful to present the information in the form of a listing, noting the component name followed by specific material identifier. We believe stating only a generic class (e.g., "PVC") is not adequate because there are many formulations of material compositions.

Physical Specifications

When describing physical specifications, we recommend that you include:

- dimensions: inner diameter (ID), outer diameter (OD), length, width
- types of configurations
- priming volume
- residual volume in needleless access ports
- dimensions of other features
- proximal and distal end configuration: shape, location, and diameter of outlets and side ports
- connector types: e.g., Luer lock, slip fit
- the color of all components
- any other unique physical features and specifications of the device.

Mechanical Specifications

When providing mechanical specifications, we recommend that you provide:

- strength of materials (tensile, flexural)
- strength of joints, bonds, connections, hinges, valves, locking mechanisms, etc.
- tubing elongation
- connector performance criteria; e.g., to prevent leakage
- burst pressure
- puncture/reseal limits of septa
- flow characteristics
- material hardness
- crimping/flexion when intended for use with infusion pumps.

Design Features

We recommend that you describe the design features of your device and any similarities or differences between those features and features of similar legally marketed devices of the same type, which may affect safety and effectiveness.

6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of intravascular administration sets and accessories addressed in this document. The information we recommend you include in your 510(k) to address these identified risks are given in this guidance document, as shown in the table below. We recommend that you conduct a risk analysis to identify any other risks specific to your device and submit the results of this analysis. If you elect to use an alternative approach to address a particular risk identified in this document or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

Identified risk	Recommended mitigation measures
Device malfunction	Section 7. Bench Testing
Adverse tissue reaction	Section 11. Biocompatibility
Infection	Section 8. Microbial Ingress Testing Section 9. Simulated Clinical Use Testing Section 10. Sterilization
Improper use	Section 12. Labeling

7. Bench Testing

We recommend that you conduct all testing under both a dry test condition and a wet environment simulating body fluids or fluids being administered. We recommend that you evaluate your device compared with a similar legally marketed device, using worst case simulated static and dynamic forces to the failure point of the components. We also recommend that you describe how you determined the worst case conditions used. Testing should assess:

- the force to attach and detach connections
- the force to activate and deactivate any safety features present
- the number of injection port accesses to failure for needleless port with valves, diaphragms, or membranes
- the pressure and leak tolerance for pre-slit septa under extreme conditions of use.

In addition, when your device is intended for use with other manufacturer's blunt cannulae, we recommend that you conduct the pressure and leak tolerance testing for pre-slit septa under extreme conditions of use with those blunt cannulae.

Where appropriate to your device's intended use or design, we recommend that you follow the standards listed below or equivalent measures, in addition to the testing described above.

- ISO 8536-4: 2004, Infusion Equipment for Medical Use, Part 4
- ANSI/AAMI BF7: R2002, American National Standard for Blood Transfusion Micro Filters
- ISO 1135-4: 2004, Transfusion Equipment for Medical Use
- ISO 594, Conical Fittings with a 6 % (Luer) Taper for Syringes, Needles, and Certain Other Equipment.

8. Microbial Ingress Testing

A needleless device that facilitates bi-directional fluid flow may increase the patient's risk of infection because these features allow the entry of microorganisms into the sterile fluid path. We recommend that you conduct microbial ingress testing of these devices. This testing is intended to simulate repeated access.

We recommend that you provide results from a simulated use test for microbial ingress in your device. Testing should simulate the use of the device in a clinical setting, i.e., the number of microbial challenges in the study should approximate the number of user interactions with the access site that would be expected clinically. The testing should demonstrate that the disinfection procedures you use are effective. We recommend that you provide an analysis of the study results and a summary of the results and conclusions.

We recommend that you provide a detailed protocol for your study, which describes the:

- study procedure for the subject device
- amount and identity of challenge organisms
- methods used to prepare the challenge organisms commonly associated with contaminated needleless access devices, i.e. 2 gram negative and 2 gram positive organisms.
- method of device contamination/inoculation for all sites of device inoculated
- access procedure
- time and culture procedures
- rationale for the challenge microorganisms used as inoculum (minimum of 10^3 per device)
- type of environment in which the study was conducted
- positive (non-disinfected device) and negative controls used in the study
- rationale for the sample size used in the study
- validation (using microbiological techniques) of the disinfecting procedures for insertion and reinsertion into the needleless access site.

9. Simulated Clinical Use Testing

For devices that include sharps injury prevention features, we recommend that you conduct simulated clinical use testing; provide an analysis of the results; and a summary of the results and conclusions. For information about this kind of testing, see Training for Development of Innovative Technologies Project,[9] and the guidance entitled, **Supplementary Guidance on Premarket Notifications for Medical Devices with Sharps Injury Prevention Features**.[10]

We recommend that you provide a detailed protocol for your study that addresses variables in the patient and health care professional user populations. If the device will be exposed to many conditions of use, we recommend that you assess the variables to accurately judge the performance of the device under these conditions. These variables include, but are not limited to training, learning curve, and the experience of users. For information about device design and human factors, see ANSI/AAMI HE48-1993: Human factors engineering guidelines and preferred practices for the design of medical devices and the FDA guidance entitled, **Do It By Design - An Introduction to Human Factors in Medical Devices**.[11]

[9] http://www.tdict.org
[10] http://www.fda.gov/cdrh/ode/guidance/934.html
[11] http://www.fda.gov/cdrh/humfac/doit.html

We recommend that you devise protocols, whenever possible, based on statistical considerations, such as sample size, response variables, pass-or-fail criteria, comprehensive report forms, proper controls, and appropriate statistical test methods. (This guidance does not provide a detailed discussion of statistical considerations).

10. Sterilization

FDA recommends that you provide sterilization information as described in the guidance, **Updated 510(k) Sterility Review Guidance K90-1**.[12] The device should be sterile, with a sterility assurance level (SAL) of 1 x 10^{-6} using a sterilization cycle that has been validated in accordance with the Quality Systems (QS). 21 CFR 820.30.

11. Biocompatibility

We recommend that you conduct biocompatibility testing for your device as a prolonged duration, indirect blood path contacting device as described in the guidance entitled, **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing**.[13] You should select the tests appropriate for the duration and level of contact and submit your pass/fail criteria. We also recommend that you document the results in your design history file as a part of the QS (21 CFR 820.30). If identical materials are used in a predicate device with the same type and duration of contact, you may identify the predicate device in lieu of performing biocompatibility testing.

12. Labeling

Labeling must provide sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following information will assist you in meeting the requirements of 21 CFR Part 801.[14]

Intended Use

We recommend that you clearly state the intended use of your device and include the indications for use and include the intended (target) population, e.g., pediatric patients. If your device is intended for use with a specific blunt cannula, infusion pump, or other device, we recommend that you identify that device.

Description of the Device

[12] http://www.fda.gov/cdrh/ode/guidance/361.html
[13] http://www.fda.gov/cdrh/g951.html
[14] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of part 801.

We recommend that the description of the device include:

- type
- set length, in inches and millimeters
- inner diameter (ID)
- outer diameter (OD)
- drops/ml
- priming volume
- filter
- needle gauge and length
- single use only, nontoxic, non-pyrogenic fluid path, where applicable
- sterile, if package is intact, undamaged, and protective caps are secure.

Directions for Use

We recommend that your directions for use include:

- a step-by-step procedure for use of the device
- a step-by-step procedure for the use of needleless access components, where applicable
- special patient instructions (including instructions for contacting the healthcare provider if indicated for home use)
- the recommended frequency of replacing the IV set or needless access device, as appropriate, for example “per CDC guidelines or facility protocol”
- the duration of use and frequency of replacing IV sets when used for the administration of lipids, blood, or blood products according to their labeling
- directions for replacing the sterile cap (needleless access devices without pre-slit septa only) with each use unless a mechanism is in place to keep the cap sterile
- instructions for cleaning and disinfecting y-sites
- instructions for cleaning and disinfecting pre-slit septa, where applicable
- instructions for discarding a used device.

We also recommend that you include illustrations, pictures, posters, cards, and other visual aids that clarify and reinforce the directions for use.

Precautions

We recommend that labeling include any special limitations related to opacity or the type of solutions used with the device (e.g., light sensitive solutions, fat emulsions, lipids, blood, and blood products). We also recommend that labeling identify the presence of the

plasticizer DEHP in the fluid pathway of PVC tubing, because leaching of the plasticizer is possible on contact with lipids.

Warnings

We recommend that labeling warn against use with high-pressure infusion systems, where applicable.

For administration sets that may be used with infusion pumps with no restricted flow feature, labeling should include warnings related to unrestricted flow and instructions for use with gravity flow.

Labeling of Shelf Containers

For labeling a multi-unit or shelf container, we recommend that you include:

- a description of the contents, in words and/or pictures
- the number of infusion sets or accessories
- instructions for use in each shelf container
- terms describing whether the units are sterile and single use
- the year and month of sterilization
- the recommended storage conditions, if any.

Appendix I. Glossary of Terms

The terms here are defined for the purpose of this guidance document only, unless otherwise noted.

Anti-Siphon Valve. An accessory to an IV administration set that protects against unregulated gravity fluid infusion or blood.

Backcheck Valve. An accessory to an IV administration set that allows for uni-directional fluid flow and serves as a multiple access site for the injection of fluids.

Blood Administration Set. A device used as part of a system to administer and filter blood and/or blood components to a patient.

Capped Luer Connector. A needleless system that is the same as those commonly used at the catheter end of IV sets. The mating Luer fitting of a syringe or secondary set can be aseptically connected directly to the Luer port. A manual clamp is included on the tubing above the Y-site to prevent fluid flow while attaching or detaching a connection; when the port is not in use, it is capped to maintain a closed system. Alternately, a pre-pierced septum injection adapter, recessed needle injection adapter, or valved connector can be aseptically placed on the Luer connector of the capped Luer Y-site to provide a self-sealing site. See also p.328, Needlestick-prevention Devices, ECRI Health Devices. 23: (8–9) Aug./Sept. 1994.

Filter. An accessory to or component of an IV administration set; a device that is designed to eliminate entrapped air or inadvertent particulates and microbial contaminants from solutions prior to patient administration.

Intravascular Administration Set. A device used to administer fluids from a container to a patient’s vascular system through a needle or catheter inserted into a vein. The device may include a needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an IV set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an IV bag or other infusion fluid container (21 CFR 880.5440).

IV Flow Regulator. An accessory (to an IV administration set) that controls the flow of intravenous solutions.

IV Manifold. An accessory to an IV administration set that provides multiple access ports and regulates the directional flow of fluids for simultaneous/alternate intravenous therapy.

IV Stopcock. An accessory to an IV administration set that regulates the directional flow to a patient's vascular system and provides an access port(s) for the administration of solutions.

Needleless System. Components of a device that provide repeated access to a patient's vascular system without the use of sharps. Fluid flow through the system may be uni-directional or bi-directional, with the latter enabling the user to administer or withdraw fluids or medication. Needleless mechanisms include three types: pre-pierced septum and blunt cannula; valved connector (also called reflux valve); and capped Luer connector.

Prepierced Septum and Blunt Cannula. A needleless system in which a blunt cannula is placed on the syringe or secondary set. It can be aseptically inserted into a pre-pierced septum on a Y-site, injection adapter, or extension set.

Valved Connector (also called reflux valve). A needleless system in which a valved connector prevents the flow through the connector until a mating Luer connector is aseptically inserted; the valve then opens.

Vial Adapter. A device designed to facilitate the withdrawal of drugs or solutions from a vial and may have a needleless device component as part of its design.

Appendix II. Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
CDC	Centers for Disease Control and Prevention
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
DAGID	Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
DEHP	Diethylhexylphthalate
DSMICA	Division of Small Manufacturers, International, and Consumer Assistance
ECRI	Emergency Care Research Institute
FDA	Food and Drug Administration
ID	Inner Diameter
IRB	Institutional Review Board
ISO	International Organization for Standardization
IV	Intravascular
OD	Outer Diameter
ODE	Office of Device Evaluation

Appendix III. Recommended Submission Checklists for Intravascular Administration Sets

Device Description

Item Included	Yes	No	Comments
Narrative description			
Photographs or labeled diagrams			
Insertion tube, if applicable			
Sample provided			

Physical Specifications

Item Included	Yes	No	Comments
Dimensions and volumes			
Proximal and distal end configurations			
Connector type			
Color (purpose)			
Opacity			
Markings and scales			
Special features			

Mechanical Specifications

Item Included	Yes	No	Comments
Strength of materials			
Stress characteristics			
Fluid flow rate			
Lubricant identified (if applicable)			

Material Specifications (cont.)

Item Included	Yes	No	Comments

Tensile strength			
Burst test			
Leakage test			
Security of attachments			
Hardness			
Percentage tubing elongation			
Crimping or flexing with clamp			
Cyclic performance with pump			

Labeling

Item Included	Yes	No	Comments
Device name			
Intended use			
Type			
Size, set length			
Inner diameter			
Outer diameter			
Drops/ml			
Priming volume			
Filter			
Needle gauge and length			
Quantity			
Single use only			
Sterile, non-toxic			
Non-pyrogenic fluid path			
Directions for use			
Promotional materials			
Plasticizer			

Sterilization

Item Included	Yes	No	Comments
Method (EtO/Gamma)			
Validation Method			
SAL			
Dosage (if gamma irraditated)			
Residues (if ethylene oxide)			
Pyrogen-free method			
Packaging materials			

Tabular Comparison to a Legally Marketed Device

Item Included	Yes	No	Comments
Identified as appropriate legally marketed device			
Side-by-side comparison			
Features			
Intended use(s)			
Labeling			
All materials			
Specifications (as above)			
Performance data			
Technological aspects			
How differences may affect safety and effectiveness			

Biocompatibility Tests

Item Included	Yes	No	Comments
Cytotoxicity			

Sensitization			
Intracutaneous			
Systemic toxicity			
Hemocompatibility			
Other			

Performance Studies

Item Included	Yes	No	Comments
Risk analysis, if appropriate			
Microbial challenge, if appropriate			
Simulated use study			
Actual use study, if appropriate			