Hemodialysis Blood Tubing Sets - Premarket Notification (510(k)) Submissions

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document, contact Office of Health Technology 3: GastroRenal, ObGyn, General Hospital and Urology Devices, Division of Renal, Gastrointestinal, Obesity and Transplant at (301)796-7030.

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CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number FDA-2026-D-1877 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. You may also send an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number GUI00001649 and complete title of the guidance in the request.

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This guidance document is intended to assist industry in preparing a premarket notification submission (510(k)) for hemodialysis blood tubing set for use as the extracorporeal blood circuit during hemodialysis treatment. This guidance document identifies specific recommendations for testing and labeling to include in a 510(k) submission for hemodialysis blood tubing sets.

In general, FDA's guidance documents 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.

II. Scope

This guidance document identifies the classification regulation and product codes for hemodialysis blood tubing sets. 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 FDA guidance titled "Electronic Submission Template for Medical Device 510(k) Submission," and the webpage "Premarket Notification 510(k)" on CDRH Device Advice.

The scope of this guidance document is limited to the device described below, 21 CFR 876.5820 and product codes FJK (Set, Tubing, Blood, With And Without Anti-Regurgitation Valve) and KOC (Accessories, Blood Circuit, Hemodialysis).

> **21 CFR 876.5820 Hemodialysis system and accessories.**
> (a)(1) The extracorporeal blood system and accessories consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis (§ 876.5540) to the blood compartment of the dialyzer and back to the patient.

This generic type of device does not include any tubing or devices used for vascular access, such as hemodialysis catheters, or any tubing used for peritoneal dialysis.

III. Premarket Submission Recommendations

A. Device Description

You must include the device name (21 CFR 807.87(a)), and you should provide the appropriate product code described in Section II. You should provide the following information for your device:

- a description of the overall device system;
- a labeled diagram and the specifications for each model included in the submission, e.g., lengths, inner and outer diameters;
- functionality, including specifications (if applicable) of the individual components of the tubing system, e.g., heparin lines, infusion ports, drip chambers, infusion lines, priming sets, transducer protectors; and
- a description, such as might be found in labeling, of the hemodialysis delivery systems legally marketed in the United States that are compatible with the blood tubing set.

We recommend that you state whether the arterial and venous lines are sold separately or sold as a set.

You must also provide a comparison of your device to a legally marketed predicate device. (21 CFR 807.87(f)) Please provide your comparison in a manner that is clear and comprehensible, e.g., in tabular form listing the similarities and differences between the proposed and predicate device in terms of intended use, design features, performance specifications, and other important safety and effectiveness information. We recommend you compare the blood tubing and any accessories, e.g., clamps, connectors, transducer protectors, between your device and the predicate device.

We recommend you include the following information when comparing your device and the marketed predicate device.

- indications for use;
- materials;
- biocompatibility;
- design specifications; and
- performance specifications.

B. Performance Testing

You should describe the performance characteristics of the blood tubing set and include functional testing demonstrating the device performs as you describe. We recommend that you compare the results of performance testing data to results obtained for the predicate device. If your device performance range falls outside of the range for the predicate device, explain why this difference does not affect the safety or effectiveness, and therefore, the substantial equivalence of your device.

We recommend you perform the following tests on three or more hemodialysis tubing sets of each model you intended to market:

- pressure leak testing demonstrating that the blood tubing can withstand pressures up to 1.5 times the maximum labeled positive and negative pressures;
- endurance testing of the pump segment at maximum labeled blood flow rates and pressures;
- endurance testing, under both positive and negative pressures, of any injection ports (if applicable), using the largest recommended gauge needle identified in the labeling;
- priming volume assessment;
- tensile testing of joints and materials of all tubing segments;
- the ability of pressure transducers to withstand leakage when subjected to pressures up to 2 times the maximum labeled pressure, e.g., “strikethrough”;
- performance testing of the device’s clamps to demonstrate that they can successfully occlude the blood tubing;
- hemocompatibility for a new or significantly altered hemodialysis tubing design that affects the pattern of blood flow; and
- performance testing to evaluate the ability of the tubing to resist kinking after repeated clamping, particularly in the post-pump tubing segment.

We also recommend you evaluate a blood tubing set on each hemodialysis delivery system(s) specified in your labeling and operator’s manual by operating the unit with a blood analog fluid for four hours at 37 °C to demonstrate that tubing failure (i.e., tube kinking) does not occur. During this testing, we recommend that you inspect the tubing for kinks caused by excessive or

undersized tubing, across the length of the tubing, using a variety of hemodialyzer sizes. We also recommend that you validate the diameter of the blood pump segment to ensure that the correct blood volume is being pumped by the hemodialysis delivery system.

C. Device Materials and Biocompatibility

A description of the materials used to fabricate all components of the hemodialysis tubing set, including any colorants (e.g., inks, dyes, markings), plasticizers (including di-(2- Ethylhexyl) phthalate or DEHP) or additives should be included in your submission. We recommend you group these materials according to whether they have direct or indirect contact with the circulating blood. For each component, we recommend you:

- identify a current, legally marketed device that uses the identical materials and manufacturing methods for a similar intended use; or
- provide appropriate biocompatibility testing on a finished, sterilized device such as the testing recommended in the current FDA guidance document titled "Use of International Standard ISO-10993 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process.'"

Hemodialysis blood tubing sets are considered externally communicating devices, contacting circulating blood, long term contact (Category C) due to cumulative exposure when used to treat patients with chronic kidney disease If you are unable to identify a legally marketed predicate device that uses the exact materials and manufacturing method as described above, we recommend you evaluate the following biocompatibility endpoints:

- cytotoxicity;
- sensitization ;
- irritation or intracutaneous reactivity;
- acute systemic toxicity;
- material-mediated pyrogenicity;
- subacute/subchronic systemic toxicity;
- hemocompatibility;
- genotoxicity;
- chronic systemic toxicity; and
- carcinogenicity.

Alternatively, you may provide a justification for not conducting any of the tests identified above.

D. Sterility

FDA recommends that you provide sterilization information, as described in the FDA guidance titled "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile." We recommend the device be sterile with a sterility assurance level (SAL) of 1 x 10-6.

Blood tubing sets are in contact with circulating blood; therefore, we recommend you test the devices for pyrogenicity according to the above referenced guidance. We recommend you provide a:

- description of the method used to make the determination, e.g., limulus amebocyte lysate (LAL);
- identification of the testing endpoint reached and rationale for selecting that endpoint;
- description of the extraction technique used to obtain the test fluid from the test device, showing that all clinically relevant contact surfaces of the test device were assessed; and
- identification of the reference method used, e.g., United States Pharmacopoeia (USP), ANSI/AAMI ST72 *Bacterial endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing*, USP-NF M16015_02_01<86> *Bacterial Endotoxins Test Using Recombinant Reagents*, or relevant FDA guidance document such as "Pyrogen and Endotoxins Testing: Questions and Answers."

E. Shelf Life and Packaging

We recommend all labels for hemodialysis blood tubing include an expiration date. We recommend you provide the following tests to substantiate the validity of the proposed expiration date on devices subjected to real-time or accelerated aging:

- performance testing on aged samples including the testing listed in Section III.B. Performance Testing; and
- package integrity testing to demonstrate sterility and non-pyrogenicity.

Accelerated conditions may be used to support the labeled expiration date, as long as you include an adequate scientific rationale supporting your accelerated testing. Testing of real-time aged devices can be conducted in parallel with submission review, with results documented to file in the Design and development files, ISO 13485:2016 Clause 7.3.10 (i.e., complete test reports do not need to be submitted to FDA). See also Documentation requirements ISO 13485: 2016 Clause 4.2.[1]

[1] See 89 FR 7496. FDA issued a final rule that took effect on February 2, 2026, and amends the majority of the requirements previously in 21 CFR Part 820 (Part 820) and incorporates by reference the 2016 edition of the International Organization for Standardization (ISO) 13485, Medical devices - Quality management systems – Requirements for regulatory purposes, in Part 820. As stated in the final rule, the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the previous Part 820, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the FD&C Act.

F. Labeling

The premarket notification must include proposed labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). Proposed labels and labeling, sufficient to describe the hemodialysis blood tubing sets, its intended use, and the directions for use must be provided.

As prescription devices, hemodialysis blood tubing sets are exempt from having adequate directions for lay use required under section 502(f)(1) of the Federal Food, Drug and Cosmetic Act as long as the conditions in 21 CFR 801.109 are met. For instance, labeling must include adequate information for the intended user of the device, including indications, effects, routes, methods, frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions (21 CFR 801.109(d)).

(1) Description of the Device

We recommend the description of the device include:

- identification of the components in the package, e.g., arterial tubing, venous tubing, priming set;
- total length of the arterial and venous tubing sets;
- outer diameter (OD) of the pump segment;
- priming volume;
- identification of the hemodialysis delivery systems which are compatible with the blood tubing set;
- identification of the largest gauge needle that can be used with the injection port (if applicable);
- identification of the maximum operating pressures for the transducer protectors;
- a statement that the device is for single use only, and has a nontoxic and non-pyrogenic fluid path;
- a statement that the package is sterile, if the package is intact and undamaged, and protective caps are secure.

We also recommend you color code the device so that the patient and dialyzer connectors of the arterial blood tubing are red and the patient and dialyzer connectors of the venous blood tubing are blue.

(2) Warnings

We recommend including a warning that significant hemolysis of red blood cells can occur in kinked blood tubing, especially in the post-pump, arterial tubing segment.

As a precaution, we recommend including a warning indicating that the device is intended for single use only.

(3) Outer Package Labeling

In addition to the requirements of 21 CFR 801, we recommend that the outer package labeling include:

- device name;
- U.S. point of contact;
- storage conditions;
- priming volume;
- sterility status and method;
- sterilization date;
- a non-pyrogenic statement;
- lot number; and
- expiration date.

(4) Other Labeling Recommendations

Instructions should encourage local and institutional training programs designed to familiarize users with the features of the device and how to use it in a safe and effective manner.

You must include the indications for use in the labeling (21 CFR 801.109(c)). FDA recommends that the indications for use include the intended patient population (e.g., pediatric patients).

Appendix Glossary of Terms

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

Arterial blood tubing. The portion of the tubing set that transports blood from the patient to the hemodialyzer inlet port.

Dialysis delivery system. Dialysis delivery systems generally fall under these three types:

- **Conventional hemodialysis delivery device.** Under 21 CFR 876.5820(a)(3), a conventional hemodialysis delivery system is defined as a system that "…consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the dialysate and circulates dialysate through the dialysate compartment of the dialyzer. The dialysate delivery system includes the dialysate concentrate for hemodialysis (liquid or powder) and alarms to indicate abnormal dialysate conditions."

- **High permeability hemodialysis delivery device**. Under 21 CFR 876.5860(a)(2), a high permeability hemodialysis delivery system is defined as a machine that "…is similar to the extracorporeal blood system and dialysate delivery system of the hemodialysis system and accessories (21 CFR 876.5820), with the addition of an ultrafiltration controller and mechanisms that monitor and/or control such parameters as fluid balance, dialysate composition, and patient treatment parameters (e.g., blood pressure, hematocrit, urea, etc.)."

- **Sorbent regenerated dialysate delivery system.** Under 21 CFR 876.5600(a), "A sorbent regenerated dialysate delivery system for hemodialysis is a device that is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that consists of a sorbent cartridge and the means to circulate dialysate through this cartridge and the dialysate compartment of the dialyzer. The device is used with the extracorporeal blood system and the dialyzer of the hemodialysis system and accessories (21 CFR 876.5820). The device includes the means to maintain the temperature, conductivity, electrolyte balance, flow rate and pressure of the dialysate, and alarms to indicate abnormal dialysate conditions. The sorbent cartridge may include absorbent, ion exchange and catalytic materials."

Infusion port. A component of hemodialysis blood tubing allowing the injection of fluids through a septum.

Priming set. A segment of tubing specifically designed to prime the hemodialysis blood tubing.

Pump segment. The portion of the tubing upon which a peristaltic or rotary hemodialysis delivery pump acts.

Transducer protector. A component of hemodialysis blood tubing with a hydrophobic membrane designed to prevent blood contamination of the pressure transducers of a hemodialysis

delivery system.

Venous blood tubing. The portion of the tubing set that transports blood from the hemodialyzer outlet port back to the patient.

Guidance History*	**Date**	**Description**
Revisions to Final Guidance	July 2026	Revisions issued under Level 2 guidance procedures (21 CFR 10.115(g)(4)). The guidance reflects an update to harmonize with FDA guidance titled “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"” as well as other minor updates [primarily to remove outdated submission format information now contained in 510(k) eSTAR].
Revisions to Final Guidance	April 23, 2008	Revisions issued under Level 2 guidance procedures (21 CFR 10.115(g)(4)). The guidance reflects updates to correct citation references and add clarifications to recommendations.

*This table was implemented, beginning 2025 and previous guidance history may not be captured in totality.