



October 9, 2025

Fresenius Medical Care Renal Therapies Group, LLC
Timothy Groves
Regulatory Affairs - Senior Lead
920 Winter Street
Waltham, MA 02451

Re: K251851
Trade/Device Name: DIASAFEplusUS (F00013010)
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water Purification System For Hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: June 16, 2025
Received: September 16, 2025

Dear Timothy Groves:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Maura Rooney -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251851

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Please provide the device trade name(s).

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DIASAFEplusUS (F00013010)

Please provide your Indications for Use below.

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The DIASAFE®plusUS is intended for the preparation of ultrapure dialysis fluid (for the 2008-series machines and 5008X machines) and sterile, non-pyrogenic substitution fluid (for the 5008X machines) from pretreated water and is not intended to provide primary purification. Attention must still be given to the chemical and microbiological quality of water and concentrates and the maintenance of supply systems (e.g. RO system, central delivery system). The microbiological quality (microbial count [CFU/mL] and endotoxin measurement [EU/mL]) of the incoming water should be < 200 CFU/mL and < 2 EU/mL, respectively. The DIASAFE®plusUS can only be used with Fresenius Medical Care hemodialysis machines fitted for use with the DIASAFE®plusUS.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

1. 510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.

1.1. Submitter's Information

Name: Fresenius Medical Care Renal Therapies Group, LLC
Address: 920 Winter Street
Waltham, MA 02451-1457
Phone: (781) 460-1087
Fax: (781) 699-9635
Contact Person: Timothy Groves, Senior Lead
Preparation Date: 16 June 2025

1.2. Device Name

Trade Name: DIASAFEplusUS (F00013010)
Common Name: Fluid filter
Regulation Name: Water purification system for hemodialysis
Regulatory Class: Class II per 21 CFR § 876.5665
Product Code: FIP
Product Code Name: Subsystem, water purification
FDA Review Panel: Gastroenterology/Urology

1.3. Legally Marketed Predicate Device

The legally marketed primary predicate device is the DIASAFE[®]plus_{US} filter cleared under K243505. The predicate has not been subject to a design-related recall.

1.4. Device Description

1.4.1. Device Identification

The DIASAFE[®]plus_{US} (F00013010) is the subject of this Traditional 510(k).

1.4.2. Device Characteristics

The DIASAFE[®]plus_{US} is a non-sterile dialysis fluid filter that produces ultrapure dialysis fluid (for the 2008-series machines and 5008X machines) and sterile, non-pyrogenic substitution fluid (for the 5008X machines) for use in chronic and acute hemodialysis and hemodiafiltration. The DIASAFE[®]plus_{US} reduces microbial contaminants including endotoxin in the dialysate during treatments. The DIASAFE[®]plus_{US} is available in one (1) configuration and is compatible for use with 2008 series and 5008X hemodialysis machines. It is installed on the hemodialysis machines

using the DIAFIX™ Lock System. The DIAFIX™ Lock System is a standard feature on the hemodialysis machines and is installed during machine production.

1.4.3. Environment of Use

The DIASAFE®*plus*US is used in environments where acute and chronic hemodialysis and hemodiafiltration are performed.

1.4.4. Brief Written Description of the Device

The 2008 series hemodialysis machines use 1 DIASAFE®*plus*US. Mixed dialysis fluid is forced through an open filter port across the fibers of the DIASAFE®*plus*US. A closed bypass valve at the other end forces the dialysis fluid across the fiber membrane. Dialysis fluid passes through the porous membrane and into the filtrate compartment where it is allowed to flow through the uncapped side ports and into the hemodialyzer. Microorganisms and molecules too large to pass through the membrane are trapped in the fibers until they are flushed out, and/or disinfected during a routine cleaning cycle.

The 5008X hemodialysis system uses two (2) DIASAFE®*plus*US for preparation of the dialysis and substitution fluid which can be used for up to 100 on-line HDF treatments. The dialysis fluid is filtered by the first DIASAFE®*plus*US. A second DIASAFE®*plus*US is used to filter the ultrafiltered dialysis fluid a second time to prepare the substitution fluid. The substitution fluid can be infused in the post-dilution mode (i.e., after the blood has passed through the dialyzer), in the pre-dilution mode (i.e., before the blood enters the dialyzer), or combined.

1.4.5. Materials of Use

The DIASAFE®*plus*US is classified as an externally communicating, blood path indirect, long-term contact (> 30 days, Category C) duration, Class II device in accordance with FDA guidance *Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* (08 September 2023).

The DIASAFE®*plus*US components are composed of the materials listed in Table 1.

Table 1: DIASAFE®*plus*US Component Materials

Component	Material
Capillary Fibers (fiber bundle)	Polysulfone-polyvinylpyrrolidone blend
Filter Housing	Polypropylene
PU-Resin (potting mass)	Polyurethane
O-ring	Silicone
Welded Header (cap/flange)	Polypropylene
Plastic Tabs (tear-off brackets)	Silicone
Sealing Disc-ring	Silicone

1.4.6. Key Performance Specifications/Characteristics

Performance specifications for the DIASAFE®*plus*US are provided in Table 2.

Table 2: DIASAFE[®]plus_{US} Features

Features	Specifications
Filtration Rate	≥ 300 mL/hr/mmHg ≥ 3.75 L/min/bar
Maximum Filtration Pressure	2 bar
Surface Area	2.1 m ²
Connection System	DIAFIX™ Lock System
Dialysis Fluid Purity	Ultrapure dialysis fluid: < 0.03 EU/mL < 0.1 CFU/mL Supports generation of sterile, non-pyrogenic substitution fluid
Maximum Use Life	90 days

1.5. Intended Use

Purification of dialysis fluid (for the 2008-series machines and 5008X machines) and online hemodiafiltration (HDF) fluid (for the 5008X machines).

1.6. Indications for Use

The DIASAFE[®]plus_{US} is intended for the preparation of ultrapure dialysis fluid (for the 2008-series machines and 5008X machines) and sterile, non-pyrogenic substitution fluid (for the 5008X machines) from pretreated water and is not intended to provide primary purification. Attention must still be given to the chemical and microbiological quality of water and concentrates and the maintenance of supply systems (e.g. RO system, central delivery system).

The microbiological quality (microbial count [CFU/mL] and endotoxin measurement [EU/mL]) of the incoming water should be < 200 CFU/mL and < 2 EU/mL, respectively.

The DIASAFE[®]plus_{US} can only be used with Fresenius Medical Care hemodialysis machines fitted for use with the DIASAFE[®]plus_{US}.

1.7. Comparison of Technological Characteristics with the Predicate Device

The proposed DIASAFE[®]plus_{US} has the same principle of operation, materials, design specifications, and performance requirements as the predicate device (K243505). There are no changes to the DIASAFE[®]plus_{US} that impact performance. The changes being proposed are limited to labeling.

1.8. Performance Data

The proposed DIASAFE[®]plus_{US} is identical to the predicate DIASAFE[®]plus_{US} with respect to manufacturing, design, and materials. The proposed labeling changes do not impact the performance of the dialyzers.

1.8.1. Biocompatibility Testing

The proposed DIASAFE[®]plus_{US} is identical to the predicate DIASAFE[®]plus_{US} with respect to manufacturing, design, and materials. The proposed labeling changes do not impact the biological safety of the dialyzers.

1.8.2. Human Factors Validation Testing

The DIASAFE[®]plus_{US} was found to be safe and effective for its intended users, uses, and use environments.

1.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. The DIASAFE[®]plus_{US} is not an electrical mechanical device.

1.8.4. Software Verification and Validation Testing

Not applicable. The DIASAFE[®]plus_{US} does not contain software.

1.8.5. Animal Studies

No animal studies were performed.

1.8.6. Clinical Studies

No clinical studies were performed.

1.9. Conclusion

The intended use, indications for use, principle of operation, technological characteristics, design, materials, and performance requirements are substantially equivalent to those of the predicate device. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the DIASAFE[®]plus_{US} is safe and effective for its intended use.