May 15, 2025

Nikkiso Co., Ltd.
% Brittany Valdez Nava, MRSc
Head of Quality
Healthcare Innovation Catalysts, Inc.
8024 Summer Mill Court
Bethesda, Maryland 20817

Re: K242155
Trade/Device Name: DBB-06 PRO Hemodialysis Delivery System (DBB-06 PRO)
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: Class II
Product Code: KDI
Dated: May 13, 2025
Received: May 15, 2025

Dear Brittany Valdez Nava:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242155

Device Name

DBB-06 PRO Hemodialysis Delivery System (DBB-06 PRO)

Indications for Use *(Describe)*

The DBB-06 PRO Hemodialysis Delivery System is indicated for hemodialysis prescribed by physicians for adult patients with acute and chronic renal failure, treated in hospitals and dialysis clinics by qualified operators. The DBB-06 PRO Hemodialysis Delivery System is not indicated for pediatric patients. It is not for home use.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1.0 510(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

Company Name: NIKKISO CO., LTD.

Address:
20-3, Ebisu 4-Chome, Shibuya-ku
Tokyo 150-6022
Japan

Company Contact:
Satoko Hina
General Manager
Regulatory Affairs Department Medical Division
NIKKISO CO., LTD.
20-3, Ebisu 4-Chome, Shibuya-ku
Tokyo 150-6022
Japan
Phone: +81-3-3443-3754
Fax: +81-3-3473-4965
Email: MedicalRA@nikkiso.co.jp

Official Correspondent:
Brittany Valdez Nava, MRSc
Head of Quality
Healthcare Innovation Catalysts, Inc.
8024 Summer Mill Court
Bethesda, MD 20817

Date prepared: July 15, 2024

1.2 Subject Device Name

Trade Name: DBB-06 PRO HEMODIALYSIS DELIVERY SYSTEM

Common Name: DBB-06 PRO Hemodialysis Delivery System, including EF-02D filter and accessories

Regulation Name: Dialyzer, High Permeability Dialysate System

Regulation Number: 21 CFR 876.5860

Device Class: Class II

Product Code: KDI

Product Code Name: Dialyzer, High Permeability With Or Without Sealed Dialysate System

510(k) Review Panel: Gastroenterology/Urology

1.3 Legally Marketed Predicate Device

1.3.1 DBB-06 Hemodialysis Delivery System

The primary predicate device for the DBB-06 PRO Hemodialysis System is the DBB-06 Hemodialysis Delivery System cleared under K152938. The EF-02D endotoxin retentive filters used on the DBB-06 PRO hemodialysis delivery system, were originally cleared under K152938, to filter dialysate.

510(k) Number	K152938
Trade Name:	DBB-06 Hemodialysis Delivery System
Common Name:	High Permeability Hemodialysis System
Regulation Name:	High Permeability Hemodialysis System
Regulation Number:	21 CFR 876.5860
Device Class:	Class II
Product Code:	KDI
Product Code Name:	Dialyzer, High Permeability With Or Without Sealed Dialysate System
510(k) Review Panel:	Gastroenterology/Urology

1.3.2 2008T Bluestar Hemodialysis Machine

The secondary predicate device for the DBB-06 PRO Hemodialysis System is the 2008T BlueStar™ Hemodialysis system cleared under K231125.

510(k) Number	K231125
Trade Name:	2008T Bluestar™ Hemodialysis Machine
Common Name:	Hemodialysis Delivery Device
Regulation Name:	High Permeability Hemodialysis System
Regulation Number:	21 CFR 876.5860
Device Class:	Class II
Product Code:	KDI
Product Code Name:	Dialyzer, High Permeability With Or Without Sealed Dialysate System
510(k) Review Panel:	Gastroenterology/Urology

The 2008T BlueStar Hemodialysis Machine (K222952) is used as a reference device.

The 2008T BlueStar Hemodialysis Machine (K173972) is used as a reference device.

1.4 Device Description

1.4.1 Device Identification

The DBB-06 PRO Hemodialysis System consists of the following:

- The DBB-06 PRO Hemodialysis Machine
- EF-02D Endotoxin Retentive Filter(s)

1.4.2 Device Characteristics

The DBB-06 PRO Hemodialysis Machine is an electromechanical device. Software controls the machine during hemodialysis treatment, including fluid flow, mixing, heating, and alarms.

The EF-02D filter is a sterile dialysis fluid filter that produces ultrapure dialysate and sterile, non-pyrogenic substitution fluid as defined in ANSI/AAMI/ISO 23500. The filter reduces microbial contaminants including endotoxins in the dialysate during hemodialysis treatment. Up to two (2) EF-02D filters are used in-line as part of the DBB-06 PRO hydraulic section.

1.4.3 Indications for Use

The DBB-06 PRO Hemodialysis Delivery System is indicated for hemodialysis prescribed by physicians for adult patients with acute and chronic renal failure, treated in hospitals and dialysis clinics by qualified operators. The DBB-06 PRO Hemodialysis Delivery System is not indicated for pediatric patients. It is not for home use.

1.4.4 Environment of Use

The DBB-06 PRO Hemodialysis System including its components (EF-02D filters and accessories) is intended for use in healthcare facilities, such as hospitals and dialysis clinics where intermittent dialysis treatment is performed.

1.4.5 Brief Written Description of the Device

The DBB-06 PRO is a hemodialysis delivery system that is to be used with compatible blood tubing lines, dialyzers, acid, and bicarbonate. It is similar to other legally-marketed hemodialysis delivery systems.

The DBB-06 PRO is indicated for hemodialysis prescribed by physicians for acute or chronic renal failure patients. It is not indicated for pediatric patients and is not for home use. Dialysis can be performed using the DBB-06 PRO without additional hardware.

The DBB-06 PRO consists of a hydraulic circuit for the dialysis fluid, which is in contact with the dialysis fluid, and an extracorporeal blood circuit (blood tubing lines). This extracorporeal circuit consists of arterial and venous lines permitting blood circulation to and from the dialyzer. These blood tubing lines are a consumable of the DBB-06 PRO and have been submitted to the FDA in a separate 510(k).

The blood pump on the DBB-06 PRO draws blood from the patient's arterial access and pumps it through the extracorporeal blood circuit. The extracorporeal blood circuit can be heparinized before the blood enters the dialyzer using the heparin pump, either continuously or with a single injection. The blood flows into the venous chamber after it passes through the dialyzer. The blood is returned to the patient via venous access. The extracorporeal circuit is monitored by pressure sensors, air, blood, and bloodline detectors. This extracorporeal circuit consists of arterial and venous lines

permitting blood circulation to and from the dialyzer. The extracorporeal blood circuit is monitored by pressure sensors, air, blood, and blood tubing line detectors.

The dialysate is made by using treated water that is heated and de-aerated in the hydraulic section. The de-aerated water is then mixed with the concentrate, filtered via the ETRF, and fed into the dialyzer via the endotoxin retentive filter (ETRF) and dialysis fluid supply connector. The closed system is designed to assure that the input and output amounts of the dialysis fluid remain constant. The duplex pump supplies and drains the same amount of dialysate to and from the dialyzer. On the duplex pump drain side, the UF pump drains the amount of ultrafiltrated dialysate from the patient's blood plasma through the dialyzer. The internal pressure of the dialyzer is automatically defined based on the treatment data that is entered.

The DBB-06 PRO can be configured for both acetate dialysis and bicarbonate dialysis. It is compatible with commercially available dialyzers that are equipped with standard dialysis fluid and blood connections. The hydraulic unit within the DBB-06 PRO is cleaned and disinfected using selectable cleaning programs and is equipped with protective systems for patient safety and proper operation. The disinfection cycle is required once per day when in use and before storage. The system alerts the operator if the disinfection cycle has not been completed.

Solenoid valves switch the flow path of the dialysate according to mode of operation. The device conducts a self-test of the solenoid valves to confirm the solenoid valves open and close correctly.

The DBB-06 PRO includes an option to support assisted operation of several important functions called D-FAS (Dialysis Fully-Assist System). Priming, blood filling, rinse back and fluid bolus functions are some of the functions that can be assisted. A Patient Card reader is also included in the delivery system, which can store patient prescription and treatment data from the last 3 sessions. The operator places the patient card on the machine before preparation and the prescription data is uploaded.

The basic version of the DBB-06 PRO incorporates all of the functions necessary for double needle dialysis. The DBB-06 PRO is equipped with the protective systems and features to help ensure patient safety and correct operation.

The DBB-06 PRO complies with the following standards:

- ANSI AAMI ES 60601-1:2005+A1:2012+A2:2021,IEC 60601-1:2005+A1:2012+A2:2020
- IEC 60601-1-2:2014+A1:2020(ANSI AAMI IEC 60601-1-2:2014+A1:2021)
- IEC 60601-2-16:2018(ANSI AAMI IEC 60601-2-16:2018)

Accessory Devices

- Single (1) EF-02D Filter or Double (2) EF-02D Filters
- Compatible bicarbonate cartridges. For example, NikkiCart Bicarbonate Cartridge (K221652)
- Acid concentrates compliant with ISO 23500-4
- Compatible Bloodlines: ID 8.0mm

Optional Accessories

- Blood Volume Monitor (BVM)
- Blood Pressure Monitor (BPM)
- Dialysis Dose Monitor (DDM)

- Bicarbonate Cartridge Holder
- Patient Card Reader with Patient Card
- Heparin Pump
- Central Concentrate Supply
- Rinse port
- Sampling port
- LAN
- USB
- Water Leak Detector

1.4.6 Materials of Use

The DBB-06 PRO Hemodialysis Machine hydraulics assembly is classified as an externally communicating, indirect blood contact, and long-term exposure (> 30 days) Category C 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 (04 September 2020). A list of the hydraulic materials for the machine that come in contact with the water, concentrates, and dialysis fluid are listed below:

Materials utilized for piping [hydraulics]:

- Stainless steel
- Fluoro-rubber
- Silicone rubber
- Ceramic
- Polysulfone (PSU)
- Polyimide (PI)
- Glass
- Polypropylene (PP)
- Polyphenylene ether (PPE)
- PPE/polystyrene (PPE+PS copolymer)
- Titanium
- Polytetrafluoroethylene (PTFE)
- Ethylene-tetrafluoroethylene plastic (ETFE)
- Polyphenylsulfone (PPSU)
- Perfluoroalkoxy alkane (PFA)

Materials utilized for the blood pressure cuff (Pressurization-type & depressurization-type BP monitor)

Cuff:

- Polyurethane (PU)
- Nylon and Polyester
- Polyvinyl chloride (PVC)

Cuff hose:

- Polyurethane (PU)
- Polyvinyl chloride (PVC)
- Brass

1.5 Key Performance Characteristics

The key performance specifications and characteristics of the DBB-06 PRO Hemodialysis Delivery System are outlined in **Table 1**.

Table 1: Key Performance Characteristics

Feature	Specification/Characteristic
Blood Pump	Setting range: 40 to 600 mL/min (ID 8.0mm) Display method: Blood flow rate = Rotation of blood pump Flow rate accuracy: Set value ±10% (Inflow Pressure –150mmHg ≤ P ≤ +150mmHg) Set value -20 to 0% (Inflow Pressure -200mmHg ≤ P < -150mmHg) Flow rate might be reduced due to pump segment fatigue. -10% to 0% for typical treatment duration in the following condition. Inflow pressure: -150 mmHg minimum +150 mmHg maximum Outlet pressure: +500 mmHg maximum Protection system (Extracorporeal blood loss due to coagulation) Method: Monitoring of stoppage Monitoring of rotation (Reverse rotation) Alarm Limit: Upper Limit: Set value +10% Lower Limit: Set value -10% Reminder alarm (BP OFF, BP cover open, blood flow set 0): 20 seconds
Dialysis Flow Rate	Setting range: • Single ETRF 300 to 800 mL/min • Double ETRF 300 to 700 mL/min Flow rate accuracy: Set value ±10% Protective system (Ultrafiltration) Method: Monitoring of Duplex pump rate with cell Alarm limit: Upper limit: +10% Lower limit: -10% Protective system (Ultrafiltration) Method: Monitoring of Duplex pump valve leak with cell Alarm limit: 0.7V Dialysate Flow Rates can be automatically set based on the provider's prescription through the Dialysate Flow Adaptation Function (optional).
Net Fluid Removal	0 to 4000 (mL/hr), Profiled UF

<table>
<tr><td>Dialysis Time</td><td>Hemodialysis: 0 to 10 hours, time can be adjusted manually</td></tr>
<tr><td>Dialysis Fluid Composition</td><td>Volumetric, continuous with duplex pump
Total conductivity range (mS/cm): 12.7 to 15.2
Monitoring conductivity average accuracy: ±-0.2mS/cm
Maximum concentrate deviation alarm limit is set at ±5%

<table><tr><td colspan="2">Proportional Mixing System</td></tr><tr><td>Acid</td><td>Setting range : 12.7 to 15.2 mS/cm
Measurement accuracy : ±0.2 mS/cm (±2 mmol/L)</td></tr><tr><td>Bicarbonate</td><td>Volumetric, automatically mixed to saturation:
Setting range : 2.3 to 7.0 mS/cm
Measurement accuracy : ±0.1 mS/cm</td></tr></table></td></tr>
<tr><td>Dialysis Fluid Temperature</td><td>Setting range: 33.0 to 40.0°C (91.4 to 104 °F)

Protective system (Dialysis fluid temperature) Method: Monitoring of Dialysis fluid temperature

Measurement range: 10.0 to 45.0 °C (50 to 113 °F)
Measurement accuracy: Measurement value ±0.8°C (±1.4 °F) Flow rate of dialysis fluid: 500 mL/min at a constant ambient temperature

Fixed alarm limit:
Upper limit: 41 °C (105.8 °F)

Auto alarm limit:
Upper limit: Set value +1 °C (+1.8 °F)
Lower limit: Set value -1 °C (-1.8 °F)</td></tr>
<tr><td>Heparin Delivery Rate</td><td>Setting range: 0.0 to 9.9 mL/h
Output rate accuracy: Set value ±10%
Back pressure: +500 mmHg

Syringe type:
30 mL (Luer Lock) or 20 mL (Luer Lock) (optional)
20 mL (Luer Lock) or 10 mL (Luer Lock)

Bolus process: 0.0 to 9.9 mL
Max. bolus accumulation capacity: 1 x syringe capacity (30 mL, 20 mL, or 10 mL)

Alarm limit:
Upper limit: +20%
Lower limit: -20%</td></tr>
<tr><td colspan="2">Blood Volume Monitor (BVM) – optional</td></tr>
<tr><td>BV Function</td><td>Measurement principle: Near-infrared reflection method
Applicable blood flow rate range: 40 to 600mL/min
Applicable hematocrit range: 15 to 50%
dBV monitoring accuracy: ±2.3dBV% (Double needle)

Alarms : dBV drop alarm 1, dBV drop alarm 2, dBV change rate alarm.</td></tr>
</table>

Blood Pressure Monitor (BPM) - optional	
Pressurization-type blood pressure monitor	Measurement technology: Oscillometric Measurement method: Step-up measurement: Linear Pressurized Measurement method Step-down measurement: Step-Depressurized Measurement method Pressure display range: 0 to 300 mmHg Pressure display accuracy: Less than ±3 mmHg Blood Pressure measurement accuracy: Conform to ISO 81060-2:2018/Amd.1:2020 Average within ±5mmHg compared to auscultatory method. Delta standard deviation within 8 mmHg. Measurement range: Systolic blood pressure (SYS) 40 to 280 mmHg Mean arterial pressure (MAP) 10 to 280 mmHg Diastolic blood pressure (DIA) 10 to 235 mmHg Pulse rate: 30 to 200 beat per minute Pulse rate accuracy: ±2% or ±2 beats (whichever is greater) Degree of protection against electrical shock (Blood pressure cuff): Defibrillation - proof Type BF Applied part Alarm Limits: SYS alarm upper limit:200 mmHg SYS alarm lower limit: 80 mmHg MAP alarm upper limit: 180 mmHg MAP alarm lower limit: 60 mmHg DIA alarm upper limit: 160 mmHg DIA alarm lower limit:50 mmHg Pulse rate alarm upper limit 170 beats per minute Pulse rate alarm lower limit 50 beats per minute
Depressurization-type blood pressure monitor	Measurement technology: Oscillometric Measurement method: Linear deflation method Pressure display range: 0 to 300 mmHg Pressure display accuracy: Less than ±3 mmHg Blood Pressure measurement accuracy: Conform to ISO 81060-2:2018/Amd.1:2020 Average within ±5mmHg compared to auscultatory method. Delta standard deviation within 8 mmHg. Measurement range: Systolic blood pressure (SYS): 60 to 250 mmHg Mean arterial pressure (MAP): 45 to 235 mmHg Diastolic blood pressure (DIA): 40 to 200 mmHg Pulse rate: 40 to 200 beat per minute Pulse rate accuracy: ±2% or ±2 beats Degree of protection against electrical shock (Blood pressure cuff): Defibrillation - proof Type BF Applied part

	Alarm Limits: SYS alarm upper limit:200 mmHg SYS alarm lower limit: 80 mmHg MAP alarm upper limit: 180 mmHg MAP alarm lower limit: 60 mmHg DIA alarm upper limit: 160 mmHg DIA alarm lower limit:50 mmHg Pulse rate alarm upper limit 170 beats per minute Pulse rate alarm lower limit 50 beats per minute
Daily Dose Monitor (DDM) - optional	
Daily Dose Monitor (DDM) - optional	Measurement principle: Absorptiometry Applicable Treatment mode : HD Applicable Kt/V range: 0 to 3.0 Applicable Kt range: 0 to 300.0 Applicable K range: 0 to 999.9 Kt/V monitoring accuracy : ±0.1 (Kt/V 0 to 1) ±10% (Kt/V 1 to 3) eKt/V range : 0 to 30 Applicable URR range: 0% to 100% URR monitoring accuracy : ±5%
Assisted Functions	
Dialysis Fully Assist System (DFAS)	The DBB-06 PRO has a series of fully-assisted functions (minimal manual interaction) functions that are programmed to assist users in order to improve efficiency and accuracy in completing these functions. This feature is called the D-FAS (Dialysis Fully Assist System). Functions that are included in the D-FAS include: • Priming: D-FAS automatically primes the extracorporeal circuit without operator intervention. The drain port and priming clamp are controlled by software. • Blood Filling: The operator connects the arterial and venous patient access and starts D-FAS blood filling. D-FAS blood filling can remove the priming solution automatically through the dialyzer, minimizing the patients UF removal. • Rinse back: D-FAS rinse back returns the blood in the extracorporeal circuit back to the patient through the arterial and venous patient access without any operator intervention. • Fluid bolus: D-FAS fluid bolus can deliver a defined volume (set by the physician) of sterile saline to the patient automatically as needed.
Dialysate Flow Adaption	This function automatically sets dialysate flow rate from the multiplying factor of blood flow rate when [Flow adaption] key is ON. As compared to the predicate device where the end user would manually set the dialysate flow rate, this function automates this step. Automation of this step is intended to simplify and streamline

	the process and was evaluated in software validation. This feature does not impact the intended use and does not raise any new questions of safety or effectiveness when compared to the primary predicate device.
Patient Card and Patient Card Reader - optional	
Patient Card Reader	This function supports the import of prescription data into the DBB-06 PRO via a personal patient card without cable connections. Upon treatment completion, the last three treatments are available on the contactless (RFID technology) patient card. The Patient Card Reader can also write a name and ID number to a blank card and save changes to the prescription.
Patient Card	Communication method: NFC (Near Field Communication) ISO/IEC 14443 Type A International Standard EU: RED(2014/53/EU) USA: FCC ID:AK8RCS632U CANADA: IC No.:409B-RCS632U Frequency: 13.56MHz Modulation System: Transmission-ASK, Reception-ASK Field Strength: 64.5 dBμV/m (Distance 3 m) Communication speed ISO/IEC 14443 TypeA:106kbps Communication Field Maximum 25 mm Using Card: Mifare Classic (Standard) 4K Card capacity 4096 byte (the usable range is 3440 bytes.)

1.6 Comparision of Key Technological Characteristics with the Predicate Device(s)

1.6.1 DBB-06 Hemodialysis Delivery System

The DBB-06 PRO (subject device) and the DBB-06 Hemodialysis Delivery System (predicate device) have identical intended use and indications for use. The subject and predicate devices have similar designs, configurations, technological characteristics, and principles of operation.

The DBB-06 PRO Hemodialysis Delivery System (hereinafter DBB-06 PRO or subject device) was modified from the Predicate DBB-06. These devices have the following same features:

- Indications for Use
- Operating Principle
- Basic System Design as follows;
    - double needle dialysis
    - BVM (Blood Volume Monitor) (optional)
    - BPM (Blood Pressure Monitor) (optional)
    - DDM (Dialysis Dose Monitor) (optional)
    - Level adjuster pump
    - Heparin pump
    - Bicarbonate powder cartridge holder
    - Central concentrate supply

Main Changes from DBB-06 Hemodialysis Delivery System (K152938)

The following are the changes in the DBB-06 PRO as compared to the predicate DBB-06.

- D-FAS (Dialysis Fully-Assist System)
- Dialysate Flow Adaptation Function (optional)
- Patient Card and Patient Card Reader
- Pressurization-type Blood Pressure Monitor
- Software Changes
- Material Changes

The difference in technological characteristics have been evaluated through performance bench testing. The results of these studies verify that these differences do not raise new or different questions of safety and effectiveness when the DBB-06 PRO is used as intended.

1.6.2 2008T Bluestar Hemodialysis Machine

The DBB-06 PRO (subject device) and the 2008T Bluestar™ Hemodialysis Machine (predicate device) have similar intended use and indications for use. The 2008T Bluestar™ Hemodialysis Machine has similar designs, configurations, technological characteristics, and principles of operation to the following functions available in the DBB-06 PRO:

- D-FAS (Dialysis Fully-Assist System)
- Dialysate Flow Adaptation Function (optional)
- Patient Card Reader

The difference in technological characteristics have been evaluated through performance bench testing. The results of these studies verify that these differences do not raise new or different questions of safety and effectiveness when the DBB-06 PRO is used as intended.

1.7 Sterilization Testing

1.7.1 DBB-06 PRO Hemodialysis Machine and EF-02D Filters

The DBB-06 PRO Hemodialysis Machine is provided non-sterile. The machine is disinfected using the pre-programmed machine disinfection cycle. The machine disinfection cycle has been validated to ensure an appropriate log reduction of bacteria in the hydraulics of the machine.

The EF-02D Filters are provided sterile. The filters are sterilized using gamma (γ) irradiation. The filter sterilization has been validated to ensure the appropriate Sterility Assurance Level (SAL) of 10^{-6} for devices in contact with the dialysis fluid.

1.8 Performance Data

1.8.1 Performance – Bench Testing

Performance testing to support the determination of substantial equivalence of the DBB-06 PRO Hemodialysis Delivery System is summarized in the table below.

Table 2: DBB-06 PRO Performance Testing Summary

Component	Test Conducted	Test Objective
DBB-06 PRO Machine	System Level Performance Testing	Ensure the device performs in accordance with the product requirements and design inputs
	Disinfection Validation Testing	Ensure the disinfection cycles preset in the machine properly reduce microorganism populations
	Environmental and Transportation Studies	Verify that the device packaging protects the device from damage during shipment and storage
	Chemical Characterization/Material Compatibility	Ensure that the materials of the machine are compatible with the chemicals that they contact to determine the potential risk for an unacceptable adverse biological response in a patient resulting from contact between medical device components and the body
EF-02D Endotoxin Retentive Filters	Sterilization Validation	Confirms the appropriate Sterility Assurance Level (SAL) of the medical device. The testing establishes the pertinent sterilization parameters for health care reprocessing instructions.
	Environmental and Transportation Studies	Verify that the device packaging protects the device from damage during shipment and storage
	Bacterial Retention Testing	Verify that the filter can produce ultrapure dialysate from dialysis fluid spiked with bacteria exceeding the allowable limit of < 100 CFU/mL (ANSI/AAMI ISO23500-5:2019)
	Endotoxin Retention Testing	Verify that the filter can produce ultrapure dialysate from dialysis fluid spiked with endotoxin exceeding the allowable limit of < 0.5 EU/mL (ANSI/AAMI ISO23500-5:2019)
	Ultrafiltration Rate	Verify that the filter has an acceptable aqueous Ultrafiltration rate (KUF)
	Dialysis Fluid Composition	Measure the composition of dialysis fluid after passing through two (2) filters
	Chemical Characterization/ Material Compatibility	Ensure that the materials of the filter are compatible with the chemicals that they contact to determine the potential risk for an unacceptable adverse biological response in a patient resulting from contact between medical device components and the body

1.8.2 Biocompatibility Testing

Biocompatibility testing for the DBB-06 PRO Hemodialysis Delivery System patient contacting components was conducted in accordance with ISO 10993-1:2018 and FDA guidance document *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 DBB-06 PRO Hemodialysis Machine hydraulics assembly is classified as an externally communicating, indirect blood contact, and long-term exposure (> 30 days) Category C device.

The blood pressure cuffs are only intended to contact intact skin for transient use of blood pressure monitoring during hemodialysis treatment, they are classified as a surface, intact skin, limited contact (≤24 hr) duration, Class II (Category A) device.

The following testing was conducted to support the biological safety of the DBB-06 PRO Hemodialysis System:

- Cytotoxicity
- Sensitization, Guinea Pig Maximization
- Intracutaneous Irritation
- Material-Mediated Pyrogenicity
- Acute and Sub chronic Systemic Toxicity
- Genotoxicity
    - Bacterial Reverse Mutation (Ames)
    - Mouse Lymphoma
- Hemocompatibility, ASTM Hemolysis (Indirect)
- Chemical Characterization
- Toxicological Risk Assessment

1.8.3 Human Factors Validation Testing

Human Factors validation testing performed on the DBB-06 PRO Hemodialysis System found no impact on the safe and effective use of the device. NIKKISO concludes that the system is safe and effective for the intended users, uses, and use environments.

1.8.4 Electrical Safety and Electromagnetic Compatibility (EMC)

The DBB-06 PRO Hemodialysis System was evaluated for electromagnetic compatibility (EMC) in accordance with IEC 60601-1-2:2020.

Additional electrical testing was conducted in accordance with IEC TR 60601-4-2:2016.

1.8.5 Software Verification and Validation Testing

Unit, integration, and system level software verification testing were performed to demonstrate the efficacy of the software and to confirm operation of the machine. The following testing was performed:

- Functional and Performance Verification
- Regression Testing
- Code Reviews

Software verification information within this submission is provided in accordance with the following FDA guidance documents:

- Content of Premarket Submissions for Device Software Functions (14 June 2023)
- Guidance for Off-The-Shelf Software Use in Medical Devices (11 August 2023)
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (27 September 2023)

1.8.6 Animal Studies

No animal studies were performed on this device.

1.8.7 Clinical Studies

Clinical studies were not performed on the device.

1.9 Conclusions

Based on above discussion and enclosed sections regarding substantial equivalence to the predicate device, NIKKISO CO., LTD. concludes that the DBB-06 PRO Hemodialysis Delivery System is substantially equivalent to the Nikkiso DBB-06 Hemodialysis Delivery System and the 2008T Bluestar and does not raise any new or different questions of safety or effectiveness.