July 19, 2019

Nipro Medical Corporation
Jessica Oswald-McLeod
Director, Quality and Regulatory
3150 NW 107th Ave.
Doral, FL 33172

Re: K182940
Trade/Device Name: Surdial DX Hemodialysis System
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: Class II
Product Code: KDI
Dated: June 14, 2019
Received: June 17, 2019

Dear Jessica Oswald-McLeod:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Carolyn Y. Neuland, Ph.D.
Assistant Division Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K182940

Device Name
Surdial DX Hemodialysis System

Indications for Use *(Describe)*
The SURDIAL DX Hemodialysis System is indicated for implementing and monitoring hemodialysis treatments in patients with acute and chronic kidney (renal) failure. The system can be used in hospitals, healthcare facilities and outpatient dialysis centers when prescribed by a physician and used by qualified operators. The SURDIAL DX accommodates the use of both low flux and high flux hemodialysis.

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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# Section 5 510(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.

## 5.1. Submitter's Information

**Name:** Nipro Medical Corporation
**Address:** 3150 NW 107th Ave.
Doral FL 33172 USA
**Phone:** 305-599-7174
**Contact Person:** Jessica Oswald-McLeod
Director, Quality Assurance and Regulatory Affairs
**Email:** JessicaO@nipromed.com
**Preparation Date:** July 19, 2019

## 5.2. Device Name

**Trade Name:** SURDIAL DX Hemodialysis System
**Common Name:** Dialyzer, High Permeability with or without Sealed Dialysate System
**Classification Name:** High Permeability Hemodialysis System
**Regulatory Class:** Class II per 21 CFR §876.5860
**Product Code:** KDI
**Classification Panel:** Gastroenterology/Urology

## 5.3. Legally Marketed Predicate Device

**B Braun Dialog+® Hemodialysis System (K083460)** is the predicate for the SURDIAL DX Hemodialysis Machine.

## 5.4. Device Description

The SURDIAL DX Hemodialysis System is a single patient dialysis unit that incorporates the mechanism of mixing and producing of dialysate by quantitative mixing method and the mechanism of ultrafiltration control by use of a piston pump. The SURDIAL DX consists of 4 sections: Panel operating section, Blood circuit control section, Liquid circuit control section and Power source control section. CAN communication is used for communication between each section.

**5.4.1. Device Characteristics**
The SURDIAL DX Hemodialysis System is an electromechanical device. Software controls the machine during hemodialysis treatment, including fluid flow, mixing, heating, and alarms.

**5.4.2. Environment of Use**
The SURDIAL DX Hemodialysis System is to be used in hospitals and healthcare facilities by qualified operators.

**5.4.3. Brief Written Description of the Device**
The SURDIAL DX Hemodialysis System has a built-in dialysate preparation system and piston pump ultrafiltration (UF) control system. The SURDIAL DX controls and monitors the hydraulic circuit and extracorporeal blood circuit. It provides hemodialysis treatment by controlling and monitoring both the dialysate circuit and the extracorporeal blood circuit. The machine pumps blood from the patient's body through an extracorporeal circuit containing the dialyzer. The dialyzer contains a semi-permeable membrane that uses diffusion to transfer toxins and ultrafiltration to transport excess water from the blood into the dialysate circuit. The dialysate is mixed with purified water, then heated and degassed for delivery to the dialyzer. During hemodialysis, the venous and arterial blood pressures are monitored.

**Accessories**

- Pole and hanger
- Tray
- Dialyzer holder
- Chemical solution tank belt
- Potential equalization conductor cable
- Disinfection suction tubes
- Blood pressure cuff and hose,
- Nipro Blood Tubing Set A430/V912 with transducer protectors and priming set
- NIPRO ELISIO series dialyzer K131935
- NIPRO Cellentia series dialyzers K140191 and K160444
- NIPRO ULTRA FILTER CF+609N and NIPRO ULTRA FILTER CF+220
- NIPRO DISPOSABLE LUER LOCK SYRINGE 10, 20, 30 mL K944355

**5.4.5. Materials of Use**
The SURDIAL DX Hemodialysis System is composed of the following indirect, permanent contact, externally communicating materials:

**Plastic/rubber:**
PPS Poly Phenylene Sulfid
FKM Fluororubeer
PSU Poly Sulfone
VMQ Silicone Rubber
PP Polypropylene
PPSU Poly phenyl Sulfone
PTFE Poly Tetra Fluoro Ethylene
PVDF Poly Vinylidene Difluoride
FEP Fluoropolymer
GFRPPS Poly Phenylene Sulfid added glass fiber
PPS (CF+PTFE) Poly Phenylene Sulfid added CF and PTFE

**Stainless Steel**
**Glass**
**Ceramic**

The hydraulic lines of the machines are in contact with the dialysate circuit. The dialysate circuit has prolonged, indirect blood contact. Biocompatibility testing was conducted on the contacting materials.

### 5.6. Indications for Use

The SURDIAL DX Hemodialysis System is indicated for implementing and monitoring hemodialysis treatments in patients with acute and chronic kidney (renal) failure. The system can be used in hospitals, healthcare facilities and outpatient dialysis centers when prescribed by a physician and used by qualified operators. The SURDIAL DX accommodates the use of both low flux and high flux hemodialysis.

### 5.7. Comparison of Technological Characteristics with the Predicate Device

A comparison of the technological characteristics of the SURDIAL DX Hemodialysis Machine with the B. Braun Dialog+ Hemodialysis Machine predicate device is provided in the following table.

| Item of Comparison | Subject Device: SURDIAL DX | Predicate Device: B Braun Dialog+ | **Discussion of differences** |
|---|---|---|---|
| **Performance Specification** | | | |
| Water supply | Water suitable for dialysis per | Water suitable for dialysis | Same |

| Item of Comparison | Subject Device: SURDIAL DX | Predicate Device: B Braun Dialog+ | **Discussion of differences** |
|---|---|---|---|
| | ANSI / AAMI 13959:2014 | | |
| Water supply Pressure range | 0.5 – 7.4 bar | 0.5 – 6 bar | Subject device can handle a larger range of water supply pressure, controlled by regulator. No impact on safety or effectiveness. |
| Water supply Temperature range | 5 - 30 °C / 41-86 °F | 10-30 °C /50-86 °F | Similar. The dialysis fluid is controlled with a heater. No impact on safety or effectiveness |
| Water supply Alarm "No water" | Internally monitored by pressure sensor and flow regulator | from separate monitoring device | Similar. No impact on safety or effectiveness. |
| Concentrate supply | 5 to 98 kPa (0.05 - 0.98 bar) | from container or central supply 0 – 1 bar | Similar. No impact on safety or effectiveness. |
| **Extracorporeal circulation** | | | |
| **Blood pump** | 2-roller<br>SDX only available for 8/12 mm pump tube | 2-roller pump with automatic motor switch-off when lid is opened, backstop, low hemolysis.<br>For 8/12 mm or (optional) 7/10 mm pump tubes | SDX only available for 8/12 mm pump tube |
| Blood pump pumping rate | 0, 10 to 600 mL/min (5 mL/min increment) | 50 – 600 mL/min (8/12 mm)<br>50 – 400 mL/min (7/10 mm) | Similar with finer increments of adjustments. |

| Item of Comparison | Subject Device: SURDIAL DX | Predicate Device: B Braun Dialog+ | **Discussion of differences** |
|---|---|---|---|
| | | Adjustable in 10 mL steps | No impact on safety or effectiveness. |
| Tolerance interval | < 10 % for blood pressure up to -200 mmHg | < 10 % for blood pressure up to -150 mm Hg<br>Tolerance between 10% and 25% for blood pressure up to -200 mmHg | Better control, tighter tolerance. |
| Working pressure range | Inlet pressure up to: -500 mmHg<br>Max. outlet pressure (pumping pressure) : +500 mmHg | Intake pressure up to –390 mmHg<br>Pumping pressure 0 – 1725 mmHg | Represents pump pressure which is sufficient for maximum arterial and venous pressure clinical requirements and capable of meeting alarm requirements. also safe for use considering maximum transmembrane pressure (TMP) of the dialyzer which is limited to max 500 mmHg. |
| **Heparin pump** | Nipro syringe 10 mL, 20 mL, 30 mL | 10 – 30 mL syringes | Same |
| Heparin pump pumping rate | 0.0 to 10.0 mL/h (0.1 mL/h increment)<br>Default 2.0 ml/h<br><br>Bolus<br>10 mL: Approx. 550 mL/h (Approx. 9 mL/min) | 0.1 – 10 mL/h in steps of 0.5 mL/h or 0.1 mL/h,<br><br>at bolus: 600 mL/h | Similar with greater capacity of bolus, operator selectable. Finer increments of control available to operator. |

| Item of Comparison | Subject Device: SURDIAL DX | Predicate Device: B Braun Dialog+ | **Discussion of differences** |
|---|---|---|---|
| | 20 mL: Approx. 900 mL/h (Approx. 15 mL/min)<br>30 mL: Approx. 1200 mL/h (Approx. 20 mL/min) | | |
| Tolerance interval | Flow accuracy +/- 10 % | < ±10 % | Same |
| Pressure range | 0 to 450 mmHg | 0 to +480 mmHg | Similar. No impact on safety or effectiveness. |
| **Dialysate system** | | | |
| Flow (dialysate) | 100 to 800 mL/min (100 mL/min increment) | 300 – 800 mL/min | Similar. Lower flow rate available.<br>No safety or effectiveness impact. |
| DF tolerance at dialysis machine | 0 to +10 % from the set value | ±5 % (of specified value) at 300 - 800 mL/min | The SURDIAL DX DF tolerance is selected to comply with IEC60601-2-16 clause 201.4.3.103 DIALYSIS FLUID flow |
| Bridging time of protection system | Not bridgeable during dialysis | Not bridgeable via balance chamber filling times during dialysis | Same |
| **Ultrafiltration** | Volume-controlled via balance chambers, ultrafiltration through ultrafiltration pump UF profile feature incorporated | Volume-controlled via balance chambers, ultrafiltration through ultrafiltration pump<br>Sequential ultrafiltration | Same |

| Item of Comparison | Subject Device: SURDIAL DX | Predicate Device: B Braun Dialog+ | **Discussion of differences** |
|---|---|---|---|
| | | (Bergström) / UF profile | |
| Operating range | 0 to 4,000 mL/h | 0 – 4,000 mL/h | Same |
| Overall accuracy * | F= Fbal + FUF<br><br>Fbal ± 0.15 mL/chamber cycle<br><br>FUF Ultrafiltration pump tolerance <1 % | F= Fbal + FUF<br><br>Fbal ± 0.2 mL/chamber cycle<br><br>FUF Ultrafiltration pump tolerance <1 %<br><br>* The overall accuracy F is the sum of two different errors: F = Fbal +FUF<br><br>Fbal = balance chamber deviation (measures per chamber cycles and depends on the dialysate flow)<br><br>FUF = UF pump error | Similar |
| **Dialysate Temperature** | | | |
| Temperature setting range | 34 – 39 °C/93 - 102 °F | 33 – 40 °C/91 - 104 °F | The SURDIAL DX Temperature setting range is selected to comply with IEC 60601-2-16 clause 201.12.4.4.102 DIALYSIS FLUID and SUBSTITUTION FLUID temperature |
| Temperature tolerance at | -0.5 °C to +0.5 °C/ | -0.5 °C to +1.5 °C/ +29 °F to 33 °F | Similar. |

| Item of Comparison | Subject Device: SURDIAL DX | Predicate Device: B Braun Dialog+ | **Discussion of differences** |
|---|---|---|---|
| standard ambient temperature | +31 °F to 33 °F | | No impact on safety or effectiveness. |
| Heating power | 1800 W | 1800 W | Same |
| **Dialysate conductivity** | | | |
| Operating range | Bicarbonate 2.4 – 7.0 mS/cm Total dialysate 12.5 –16.5 mS/cm | Conductivity bicarbonate 2–4 mS/cm, 4–7 mS/cm Overall conductivity 12.5 – 16 mS/cm | Similar. No impact on safety or effectiveness. |
| Tolerance | ±0.2 mS/cm or less | ±0.2 mS/cm | Same |
| Measurement | Temperature-compensated (reference temperature 25 °C/77 °F) | Temperature-compensated (reference temperature 25 °C/77 °F) | Same |
| **ABPM blood pressure monitoring** | | | |
| Cuff pressure range | 0 – 300 mmHg | 0 – 320 mmHg | Similar. No impact on safety or effectiveness. |
| Inflation pressure during first cuff inflation | 180 mmHg | 200 mmHg | Similar. No impact on safety or effectiveness. |
| Inflation pressure during subsequent measurements | Last SYS pressure +40 mmHg | Last SYS pressure +30 mmHg | Similar. No impact on safety or effectiveness. |
| Blood pressure measurement range | Systolic (SYS) 60 – 250 mmHg Average (MAP) 45 – 235 mmHg Diastolic (DIA) 40 – 200 mmHg | Systolic 45 – 280 mmHg MAP 25 – 240 mmHg Diastolic 15 – 220 mmHg | Similar. No impact on safety or effectiveness. |

| Item of Comparison | Subject Device: SURDIAL DX | Predicate Device: B Braun Dialog+ | **Discussion of differences** |
|---|---|---|---|
| Accuracy | Within ±3 mmHg | ±3 mmHg or ±2 % | Same |
| Blood pressure determination time | Typical 25 seconds (Adult with blood pressure 120/80 and 80 BPM) | Typical 25 seconds (Adult with blood pressure 120/80 and 80 BPM) | Same |
| Pulse rate determination | 40 – 200 bpm | 30 – 240 bpm | Similar. No impact on safety or effectiveness. |
| Pulse rate accuracy | The smaller of ±2% or ±2 bpm | ±2 % or 2 BPM | Same |
| Overpressure cut-off | In normal operation: 300 mmHg In single failure: 330 mmHg | 300 mmHg + 10 % | Similar. No impact on safety or effectiveness. |
| Time of alarm suppression | < 1 second | < 1 second | Same |
| Deactivation of acoustic signal | 120 seconds | 120 seconds | Same |
| Safety class | Safety class I, Type BF | Safety class I, Type BF | Same |
| **Important safety/effectiveness information** | | | |
| **Disinfection/Cleaning** | | | |
| Disinfection /cleaning | Automatic program with enforced rinse-out The parameters for the disinfectant used can be set in the system menu. | Automatic program with enforced rinse-out The parameters for the disinfectant used can be set in the service program. | Same |
| Chemical disinfection | Yes | Yes | Same |

| Item of Comparison | Subject Device: SURDIAL DX | Predicate Device: B Braun Dialog+ | **Discussion of differences** |
|---|---|---|---|
| Thermal disinfection | 96°C /205°F (fixed)<br><br>Setting time 29 to 60 min | Automatic program cycle at approx. 85 °C/185 °F at the dialyzer couplings<br><br>approx. 40 minutes | Similar.<br>No impact on safety or effectiveness. |
| External cleaning | Clean housing/ enclosure utilizing 1:100 ratio of 6% bleach (sodium hypochlorite concentrate) to water mixture. Use cleaning and disinfection agents only in accordance with the respective User Manual. Ensure that the disinfectant/ cleaning agent will be wiped off from the screen completely. | Clean housing parts, monitor, inside and outside of the rinse bucket with ethanol (max. 70 %), isopropanol (60 % to 70 %) based cleaning agents, or 1:100 bleach solution (5:25 sodium hypochlorite) as per clinic policy and procedure.<br><br>Use cleaning and disinfection agents only in accordance with the respective Instructions for Use. Ensure that the disinfectant/ cleaning agent will be wiped off from the screen completely. | Cleaning method for the SURDIAL DX produces acceptable results as per cleaning validation study.<br>No impact on safety or effectiveness. |
| **Transmembrane pressure** | | | |
| Alarm limit (max. TMP) | 0 to +700 mmHg | +300 to +700 mmHg | Similar – broader limit range. |

| Item of Comparison | Subject Device: SURDIAL DX | Predicate Device: B Braun Dialog+ | **Discussion of differences** |
|---|---|---|---|
| Alarm limit(min.TMP) | -200 to +200 mmHg | -100 mmHg | Similar – broader limit range provide for user who sets limit. |
| Limit window | Adjustable Upper: 20 to +500 mmHg Lower: -300 to +20 mmHg | Adjustable (2 % - 99 %) | Similar. SURDIAL DX utilizes a broader limit range, which is set by manufacturer absolute value. The predicate device is based on the range established by various dialyzer's manufacturer. |
| Tolerance | Calculated through PD and PV | Calculated through PDA and PV | Same |
| Bridging time of protection system | Not bridgeable during dialysis | Not bridgeable during dialysis | Same |
| Deactivation of acoustic alarm | 120 seconds | 120 seconds | Same |
| Degassing system | Vacuum deaeration method | Mechanically regulated through the degassing pump | Same |
| Tolerance | ± 20 mmHg | ± 50 mmHg | Similar – tighter tolerance than predicate device. No safety or effectiveness impact. |
| **Arterial and Venous pressure monitoring** | | | |
| **Pressure measurement at arterial inlet of dialyzer (PBE)** | N/A | Electronic pressure sensor | PBE was designed to measure the pressure increase of blood into the dialyzer caused by clotting in a dialyzer |

| Item of Comparison | Subject Device: SURDIAL DX | Predicate Device: B Braun Dialog+ | **Discussion of differences** |
|---|---|---|---|
| | | | in earlier versions of dialyzers.<br>Currently available dialyzers have better performance preventing clotting inside the equipment hence the state-of-the-art dialyzers no longer require this additional PBE function. |
| Operating range | N/A | 0 – 700 mmHg | Same as above |
| Tolerance interval | N/A | ±10 mmHg | Same as above |
| Limit | N/A | Adjustable within operating range | Same as above |
| Protection system | N/A | Test prior to start of therapy | Same as above |
| **Arterial inlet pressure (PA) measurement** | Electronic pressure sensor | Electronic pressure sensor with digital quasi-analogue display | Same |
| Operating range | –500 to +500 mmHg | –400 to +400 mmHg | Similar – broader limit range, user adjustable. |
| Tolerance | +/- 10 mmHg | ±10 mmHg | Same |
| Limit | -500 to + 500 mmHg | –400 to +400 mmHg adjustable within operating range, adjustable interval width for dynamic limits window | Similar.<br>No impact on safety or effectiveness. |
| Protection system | Electronic pressure sensor, test prior to start of therapy | Electronic pressure sensor, test prior to start of therapy | Same |

| Item of Comparison | Subject Device: SURDIAL DX | Predicate Device: B Braun Dialog+ | **Discussion of differences** |
|---|---|---|---|
| Deactivation of acoustic alarm | 120 seconds | 120 seconds | Same |
| **Venous return pressure (PV) measurement** | Electronic pressure sensor | Electronic pressure sensor with digital quasi-analogue display | Same |
| Operating range | - 500 to +500 mmHg | 20 – 390 mmHg (adjustable in service program) | Similar.<br>No impact on safety or effectiveness. |
| Tolerance | +/- 10 mmHg | ±10 mmHg | Same |
| Limit | -100 to + 480 mmHg<br>Default upper<br>300 mmHg<br>lower -10 mmHg | Alarm window around operating value<br>Configurable alarm window (20 – 200 mmHg)<br>After blood pump adjustment, the alarm window is re-centered. | Similar.<br>No impact on safety or effectiveness. |
| Protection system | Test prior to start of therapy | Test prior to start of therapy<br>Venous window of 20 – 390 mmHg.<br>Venous limits are monitored by the function and control systems. | Similar.<br>No impact on safety or effectiveness. |
| Bridging time of protection system | Not bridgeable during dialysis | Not bridgeable during dialysis | Same |
| Deactivation of acoustic alarm | 120 seconds | 120 seconds | Same |
| **Dialysate conductivity monitor** | | | |
| Protection system | Monitoring through second conductivity sensor with | Monitoring through second conductivity sensor | Same.<br>Both use a secondary sensor |

| Item of Comparison | Subject Device: SURDIAL DX | Predicate Device: B Braun Dialog+ | **Discussion of differences** |
|---|---|---|---|
| | software calibration. | with modified geometry | |
| Limit | ±5 % (of set value) | ±5 % (of set value) | Same |
| Bridging time of protection system | cannot be bridged during dialysis | cannot be bridged during dialysis | Same |
| Deactivation of acoustic alarm | 120 seconds | 180 seconds | Similar.<br>No impact on safety or effectiveness. |
| **Ultrafiltration controller** | | | |
| Protection system | Yes | Yes | Same |
| Bridging time of protection system | Not bridgeable during dialysis | Not bridgeable during dialysis | Same |
| Deactivation of acoustic alarm | 120 seconds | 120 seconds | Same |
| **Air detector system** | | | |
| Sensitivity | Alarms when any single bubble greater than 10 µL in size and when bubbles of 0.3 µL or larger, accumulate over a 1-minute period into a volume of 1, 10, 50 or 300 µL.<br>Default setting is 10 µL. | Air bubbles at > 50 µl, micro foam with cumulated volume<br>**Limit values double needle:**<br>0.2 mL at 0 – 200 mL/min SAD flow<br>0.3 mL at 200 – 400 mL/min SAD flow<br>0.5 mL at > 400 mL/min SAD flow<br>**Limit values single needle:**<br>0.7 mL at 1200 mL/min constant SAD flow | Similar. |

| Item of Comparison | Subject Device: SURDIAL DX | Predicate Device: B Braun Dialog+ | **Discussion of differences** |
|---|---|---|---|
| Protection system | Ultrasonic transmission method | Ultrasound detector, automatic cyclical checks during entire operating phase | Same |
| Bridging time of protective system | Not bridgeable during dialysis | Not bridgeable during dialysis only in end phase for approx. 30 mL (has to be activated at TSM) | Similar.<br>SURDIAL DX is not permitted bridgeable. |
| **Blood leak detector** | | | |
| Measurement | Optical | Optical | Same |
| Tolerance | +/- 100 ppm | Tolerance 10 % | See below |
| Alarm threshold | Setting range: 50 to 500 ppm (10 ppm increment) Detection point (Default: 280 ppm), (Ht 32 %) | >0.5 mL/min blood at HKT 45 %<br>>0.35 mL/min blood at HKT 25 % (AAMI) | Similar<br>Threshold setting in predicate device (0.5ml/min at 45% HKT, 0.35ml/min at 25% HKT) and by calculation the corresponding value for 0.4ml/min at 32% HKT.<br>The threshold setting in SDX between 0.05ml/min to 0.50 ml/min is 32% HKT which covers the same range as predicate device |
| Bridging time of protective system | Not bridgeable during dialysis | Not bridgeable during dialysis | Same |
| Deactivation of acoustic alarm | 120 seconds | 120 seconds | Same |

| Item of Comparison | Subject Device: SURDIAL DX | Predicate Device: B Braun Dialog+ | **Discussion of differences** |
|---|---|---|---|
| **Temperature monitor – dialysate** | | | |
| Excessive-temperature protection | Lower limit 33°C/91°F Upper limit 40°C/104 °F | 41 °C/106 °F | Similar. No impact on safety and effectiveness |
| Protection system | Temperature sensor | Temperature sensor | Same |
| Bridging time of protection system | Cannot be bridged during dialysis | Cannot be bridged during dialysis | Same |
| Deactivation of acoustic alarm | 120 seconds | 120 seconds | Same |
| **Fail-safe design feature in the event of power failure** | | | |
| Battery | Power failure backup battery | Power failure backup battery | Same |

## 5.8. Performance Data

The performance of the SURDIAL DX was evaluated according to Nipro procedures, and performance testing protocols. The device performed according to acceptance criteria in these tests, and confirmed that the device functions as intended.

### 5.8.1. Biocompatibility Testing

The SURDIAL DX Hemodialysis Machine's patient contacting components were evaluated to ISO 10993 requirements. The Unit Under Test (UUT) included the new hardware components (acid, bicarbonate and UF pumps, extended concentrate lines and ratio valves). The following testing was performed to support the biological safety of the SURDIAL DX machine:

- Cytotoxicity
- Sensitization
- Acute Systemic Toxicity
- ASTM Hemolysis
- Material Mediated Pyrogenicity
- Intracutaneous Reactivity
- Chemistry Characterization
- Biological Evaluation Report
- Toxicological Risk Assessment

**5.8.2. Electrical Safety and Electromagnetic Compatibility (EMC)**
The SURDIAL DX Hemodialysis Machine was evaluated for electromagnetic compatibility (EMC) in accordance with IEC 60601-1-2:2014. The following safety standards were also assessed for the machine:

- IEC 60601-1:2005+A1:2012 ANSI/AAMI ES 60601-1: A1:2012
- IEC 60601-1-8:2006 +A1:2012
- IEC 60601-2-16:2012
- IEC 80601-2-30:2009 +A1:2013

**5.8.3. Software Verification and Validation Testing**
The software was determined to be legacy software, and therefore a gap assessment was performed to allow updates to the software going forward to be conducted under IEC 62304 software standards. The original SURDIAL DX Software was originally developed 10 to 15 years ago (mid 2000s). The target product market was Asia, Europe and South America. The SURDIAL DX hemodialysis machine has been deployed successfully in these markets for over 10 years, with a history of reliable clinical performance.

A detailed analysis of the software and available documentation was performed, and it was determined to perform independent verification and validation. Unit, integration, and system level software verification testing demonstrates that the machine functions as intended.

**5.8.4. Environmental and Ship Testing**
Performance testing was conducted at ambient room conditions to verify normal machine function. Transportation testing was performed to verify that the machine can withstand hazards associated with the typical shipping and distribution environment.

**5.8.5. Human Factors Testing**
Human Factors testing was performed on the SURDIAL DX and found that the usability of the machine was in line with its functions, and the professional users of the machine. Nipro therefore concludes that the machine is safe and effective for the intended users, uses, and use environments.

## 5.9. Conclusions
The SURDIAL DX Hemodialysis System indications for use, intended use, and its technological characteristics are substantially equivalent to those of the predicate device namely B. Braun Dialog+. The differences between the SURDIAL DX Hemodialysis System and the predicate device do not raise any new concerns with regard to safety or effectiveness; therefore, no clinical tests were deemed necessary. Essential performance of the machine was confirmed in the IEC 60601 testing. Nipro has concluded that the SURDIAL DX Hemodialysis System is substantially equivalent to the predicate device, the B. Braun Dialog+ (K083460) Hemodialysis System within the meaning of the Medical Device Amendments Act of 1976.