November 10, 2022

Quanta Dialysis Technologies Ltd.
Sam Drew
Risk and Regulatory Manager
Tything Road, Alcester
Warwickshire B49 6EU
UNITED KINGDOM

Re: K222067
Trade/Device Name: SC+ Hemodialysis Machine, SC+ Dialysate Cartridge, SC+ Blood Tube Set
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: Class II
Product Code: KDI, FJK
Dated: October 10, 2022
Received: October 11, 2022

Dear Sam Drew:

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,

Gema Gonzalez -S

Gema Gonzalez, MS
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222067

Device Name
SC+ Hemodialysis Machine
SC+ Dialysate Cartridge
SC+ Blood Tube Set

Indications for Use *(Describe)*

SC+ Hemodialysis Machine/ SC+ Dialysate Cartridge

The SC+ Hemodialysis System is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility. Treatments must be administered under physician's prescription, by a trained person who is competent in the use of the device.

Treatment types available include: Intermittent Hemodialysis (IHD), Sustained Low Efficiency Dialysis (SLED/ SLEDD), Prolonged Intermittent Renal Replacement Therapy (PIRRT), Isolated Ultrafiltration including Slow Continuous Ultrafiltration (SCUF) and Continuous Venovenous Hemodialysis (CVVHD).

SC+ Blood Tube Set

The SC+ Blood Tube Set is a single use, disposable arterial and venous bloodline set intended to provide extracorporeal access during hemodialysis. The Blood Tube Set is compatible only with the SC+ Hemodialysis System.

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.

5 510(k) Summary

The content of this 510(k) summary is provided in conformance with 21 CFR Part 807.92

Date prepared: November 10, 2022

5.1 Manufacturer Details

Quanta Dialysis Technologies Ltd
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5.2 Contact Details

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5.3 Device Information

5.3.1 SC+ Machine & Dialysate Cartridge

Trade Name	**SC+ Machine & SC+ Dialysate Cartridge**
Common Name	**Hemodialysis Delivery System**
Product Code	**KDI**
Device	**Dialyzer, High Permeability With Or Without Sealed Dialysate System**
Classification Name	**High permeability hemodialysis system**
Regulation Number	**21 CFR §876.5860**
Device Class	**Class II**
Review Panel	**Gastroenterology/Urology**

Table 1: SC+ Device and Dialysate Cartridge general device information

Predicate Device Information:

Manufacturer	Name of Predicate Device	510(k)#	Date of Clearance
Quanta Dialysis Technologies Ltd	**SC+ Machine & Dialysate Cartridge**	**K210661**	**2021-08-12**

5.3.2 SC+ Blood Tube Set

Trade Name	**SC+ Blood Tubeset**
Common Name	**Blood Tubing Set**
Product Code	**FJK**
Device	**SC+ Blood Tubeset**
Classification Name	**Set, tubing, blood, with and without anti-regurgitation valve**
Regulation Number	**21 CFR §876.5820**
Device Class	**Class II**
Review Panel	**Gastroenterology/Urology**

Table 2: SC+ Blood Tubeset general device information

Predicate Device Information:

Manufacturer	Name of Predicate Device	510(k)#	Date of Clearance
Quanta Dialysis Technologies Ltd	**SC+ Machine & Dialysate Cartridge**	**K210661**	**2021-08-12**

Reference Device Information:

Manufacturer	Name of Predicate Device	510(k)#	Date of Clearance
Gambro Renal Products Inc.	**Prismaflex M150 set**	**K080519**	**2008-13-06**

5.4 Device Description

The SC+ is a haemodialysis delivery system intended for the provision of acute and chronic dialysis therapy, with or without ultrafiltration. The SC+ system utilises incoming Dialysis Water from an external source, with industry standard dialysis concentrate consumables, to manufacture the dialysis fluid used to deliver the treatment. The SC+ system is for use in patients with arteriovenous (AV) fistulas or central venous catheter access.

The SC+ system consists of the SC+ Machine, a single use disposable Dialysate Cartridge, and a sterile, single use, disposable Blood Tubeset.

5.4.1 SC+ Hemodialysis System

The SC+ Hemodialysis System is intended for acute and chronic dialysis therapy, with or without ultrafiltration, utilizing Dialysis Water (from standalone Reverse Osmosis (RO) units or a central RO ring main) to produce dialysate. The SC+ Hemodialysis system is for use in patients with arteriovenous (AV) fistula or central venous catheter access.

The system consists of the SC+ Machine, a single use disposable Dialysate Cartridge, and a sterile, single use, disposable Blood Tubeset.

The SC+ Machine consists of a water circuit (heater, de-aeration module, etc) blood leak detector, air in blood detector, a pneumatic interface for the dialysate cartridges, a peristaltic blood pump and various other sensors. The dialysate cartridge contains the following; conductivity monitors, interfaces for pressure and temperature measurement, membrane pumps to perform mixing/proportioning in order to produce dialysis fluid and the controlled removal of fluid from a patient with acute and/or chronic renal failure based on a physician's prescription. The dialysate fluid is manufactured using dialysis water purified externally by reverse osmosis that is heated to approximately 37°C and subsequently deaerated within the machine before entering the cartridge.

The SC+ Blood Tubeset is a single use, sterile device consisting of an arterial line, a venous line, connections to a standard dialyzer, a saline line, three pressure transducer pods integrated into a single unit, a venous drip chamber, and a line for heparin infusion.

5.5 Device Modification

This 510(k) covers the following modifications:

- Extension of permitted dialysate conductivity range
- Extended Treatment Time Range
- Increased Maximum Ultrafiltration Rate
- Increased Max Ultrafiltration Volume
- Additional (lower) Dialysate Flow Rates
- Isolated Ultrafiltration
- Dialysate composition settable by mEq/l Sodium content and by acid type
- Use Mode switching
- Adjustable settings mid-treatment
- Addition of blood leak override function
- Expansion of treatment types permitted in indications

5.6 Indications for Use

5.6.1 SC+ Haemodialysis Machine & Dialysate Cartridge

The SC+ Hemodialysis System is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility. Treatments must be administered under physician's prescription, by a trained person who is considered competent in the use of the device.

Treatment types available include: Intermittent Hemodialysis (IHD), Sustained Low Efficiency Dialysis (SLED/ SLEDD), Prolonged Intermittent Renal Replacement Therapy (PIRRT), Isolated Ultrafiltration including Slow Continuous Ultrafiltration (SCUF) and Continuous Venovenous Hemodialysis (CVVHD).

5.6.2 SC+ Blood Tubeset

The SC+ Blood Tubeset is a single use, disposable arterial and venous bloodline set intended to provide extracorporeal access during hemodialysis. The Blood Tube Set is compatible only with the SC+ Hemodialysis System.

5.7 Technological Characteristics

5.7.1 Changed SC+ device vs SC+ device as cleared in K210661

The technological characteristics of the SC+ Machine and SC+ Dialysate Cartridge are considered to be equivalent to the predicate device, SC+ device and dialysate cartridge (K210661). A summary of the similarities and differences is provided in the table below.

Characteristic	Subject Device	Predicate Device
	This submission	SC+ (K210661)
Indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration in an acute or chronic care facility	✓	✓
Use of purified water for dialysate production	✓	✓
Use of third-party accessories, including dialyzers, endotoxin retentive filters, acid and bicarbonate	✓	✓
Application of consensus standards	✓	✓
Device is software controlled and utilize Graphic User Interface (GUI).	✓	✓
Design and Construction – Blood pump, alarms, alerts, air detector mechanism, and blood leak detectors.	✓	✓

Table 3 - Technological Characteristics of the SC+ Machine and Predicate

Differences between the subject device and the predicate device:

- The subject device has a broader range of user settable treatment settings and Essential Performance characteristics:
  - Dialysate conductivity range
  - Dialysate flow rate
  - Treatment time range
  - Ultrafiltration rate
  - Ultrafiltration volume
  - Settable dialysate composition (via acid and sodium target)
- The subject device has additional features:
  - Isolated Ultrafiltration
  - Blood leak override

5.7.2 Changed SC+ Blood Tube Set vs SC+ device as cleared in K210661

The technological characteristics of the SC+ Machine and SC+ Dialysate Cartridge are equivalent to the predicate device, SC+ device and dialysate cartridge (K210661). A summary of the similarities and differences is provided in the table below.

Characteristic	Subject Device	Predicate Device
	This submission	SC+ (K210661)
Intended Use: To provide extracorporeal access during hemodialysis	✓	✓
Materials: Primary fluid path materials are Polyvinyl Chloride (PVC) and Polypropylene (PP).	✓	✓
Design & Construction: Polyvinyl Chloride (PVC) tubing of various lengths and diameters, with color coded pinch clamps, color coded injection ports, heparin line, saline line, and pressure monitoring components.	✓	✓
Sterility: Sterile, single use, non-pyrogenic.	✓	✓
Priming Volume: ≤165ml	✓	✓
Needle configuration: Double needle	✓	✓

Table 4 - Technological Characteristics of the SC+ Machine and Predicate

5.8 Summary of V&V

The following performance testing, developed in accordance with appropriate FDA guidance documents and relevant standards, has been performed on the Modified Device to support the determination of substantial equivalence:

- Essential Performance testing for dialysate composition
- Essential Performance testing for dialysate flow rate
- Essential Performance testing for Blood Flow Rate
- Essential Performance testing for Net Fluid Removal
- Essential Performance testing for Treatment Time
- Essential Performance testing for Consumables duration testing
- Blood Loss to Dialysate protective system testing
- Net Fluid Removal Protective system testing
- Patient Leakage Current testing
- Hemolysis testing
- Software verification

5.9 Conclusion

This 510(k) has demonstrated the SC+ Hemodialysis System as modified provides reasonable assurance of safety and effectiveness to demonstrate it is at least as safe and effective as the predicate device and therefore is substantially equivalent.