December 23, 2020

Quanta Dialysis Technologies Ltd.
Chris Rule, Regulatory Manager
Tything Road
Alcester, Warwickshire B49 6EU
UNITED KINGDOM

Re: K193670
Trade/Device Name: SC+ Hemodialysis System, comprised of the SC+ Hemodialysis Machine, SC+ Dialysate Cartridge, and SC+ Blood Tubeset
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI, FJK
Dated: November 20, 2020
Received: November 23, 2020

Dear Chris Rule:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193670

Device Name
SC+ Hemodialysis System, comprised of the SC+ Hemodialysis Machine, SC+ Dialysate Cartridge, and SC+ Blood Tubeset

Indications for Use *(Describe)*

SC+ Machine and 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.

SC+ Blood Tube Set:

The SC+ Blood Tubeset is a single use, disposable arterial and venous bloodline set intended to provide extracorporeal access during hemodialysis. The Blood Tubeset 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.

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6 510(K) SUMMARY

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

6.1 Submitter's Information

Submitter's Name: Company: Address:	Quanta Dialysis Technologies Ltd Tything Road, Alcester, Warwickshire, B49 6EU, United Kingdom
Contact person:	Mr. Chris Rule
Phone:	+44 (0)1789 400 043
E-mail:	chris.rule@quantadt.com
Date of summary preparation	22nd December 2019

6.2 Device Name

SC+ Hemodialysis System, comprised of the SC+ Hemodialysis Machine, SC+ Dialysate Cartridge, and SC+ Blood Tubeset

6.2.1 SC+ Machine & Dialysate Cartridge

6.2.1.1 General Device Information

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

6.2.2.1 Predicate Device Information

Trade Name	Tablo Console
Common Name	Hemodialysis Delivery System
510(k) Clearance Number	K140866
Product Code	KDI
Device	Dialyzer, High Permeability With Or Without Sealed Dialysate System
Regulation Number	21 CFR §876.5860
Classification Name	High permeability hemodialysis system
Device Class	Class II
Review Panel	Gastroenterology/Urology

6.2.3 SC+ Blood Tubeset

6.2.3.1 General Device Information

Trade Name	SC+ Blood Tubeset
Common Name	Blood Tubing Set
Product Code	FJK
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

6.2.3.2 Predicate Device Information

Trade Name	Tablo Cartridge
Common Name	Blood Tubing Set
510(k) Clearance Number	K140841
Product Code	FJK
Device	Set, Tubing, Blood, With And Without Anti-Regurgitation Valve
Regulation Number	21 CFR §876.5820
Classification Name	Hemodialysis system and accessories
Device Class	Class II
Review Panel	Gastroenterology/Urology

6.2.3.3 Reference Device Information

Trade Name	NIPRO BLOOD TUBING SET WITH TRANSDUCER PROTECTOR AND PRIMING SET, MODEL A201-A219, V801-V806, 5M9634, 5M9693
Common Name	Blood Tubing Set

510(k) Clearance Number	K072024
Product Code	FJK
Device	Set, Tubing, Blood, With And Without Anti-Regurgitation Valve
Regulation Number	21 CFR §876.5820
Classification Name	Set, Tubing, Blood, with and without Anti-regurgitation valve
Device Class	Class II
Review Panel	Gasteroenterology/Urology

6.3 Device Description

6.3.1 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 37oC and subsequently de-aerated 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.

6.4 Indications for Use

6.4.1 SC+ Hemodialysis 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.

6.4.2 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 Tubeset is compatible only with the SC+ Hemodialysis System.

6.5 Technological Characteristics

The SC+ Hemodialysis machine and Dialysate Cartridge are predicated against the Outset Tablo Console (K140866).

The SC+ Blood Tubeset is predicated against the Outset Tablo Cartridge (K140841). For mechanical hemolysis testing, the reference devices used for comparison was the Nipro tubing set (K072024).

6.5.1 SC+ Machine vs Tablo console (K140866)

The technological characteristics of the SC+ Machine and SC+ Dialysate Cartridge are considered to be equivalent to the predicate device, the Tablo Console (K140866). A summary of the similarities and differences is provided in the table below.

Technological Characteristics of the SC+ Machine

	Subject Device	Predicate Device
	SC+	Tablo Console
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.	✓	✓

Differences between the subject device and the predicate device include:

- The subject device utilizes purified water from an external source, for dialysate production, whereas the predicate device internally purifies the water.
- The subject device incorporates a validated heat disinfection process to clean the water circuit as opposed to a chemical disinfection process utilized by the predicate device.
- The dialysate cartridge pump differs to that of the predicate device. The SC+ Machine uses positive displacement pumps contained within the disposable Dialysate Cartridge, which use a combination of the reciprocating action of a membrane diaphragm between two hard surfaces and suitable valves to mix Dialysate Water with concentrates to generate dialysis fluid and to pump dialysis fluid to and from the dialyzer.
- In order to allow for the use of the Dialysate Cartridge with a compliant membrane and to allow for a higher dialysate flow rate, the flow balance control mechanism in the SC+ differs to that of the predicate device. The control and accuracy of the flow balance process has been fully validated to meet the requirements defined in IEC 60601-2-:16:2012.
- The SC+ Machine calculates the net fluid removal rate from the required mass for removal and the desired treatment time up to a maximum as stated in IEC 60601-2-16:2012. The accuracy of net fluid removal rate is independent of the dialysate flow rate. Although this is different from the predicate device, the SC+ System has undergone extensive Net Fluid Removal testing and conforms to the same standards as the predicate device.

In summary, the SC+ machine has the same intended use and is considered equivalent with regards to the technological characteristics as the predicate. The SC+ system has been fully validated and, therefore, where there are minor differences, the differences do not raise any new questions with regards to safety or effectiveness.

6.5.2 SC+ Blood Tubeset vs Tablo Cartridge (K140841)

The SC+ Blood Tubeset is predicated against the Outset Tablo Cartridge (K140841).

Technological Characteristics of the SC+ Blood Tubeset

	Subject Device	Predicate Device
	SC+	Tablo Cartridge
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	≤200 mL
Needle configuration: Double needle	✓	✓

The SC+ Blood Tubeset is considered to have equivalent technological characteristics to the predicate device. The minor differences between the devices include:

- Subject Device is mounted directly onto the blood platen of the SC+ Machine. The predicate has an organizer to facilitate interface with the machine's front panel.
- The pressure measuring component of the SC+ Blood Tubeset is different from that of the Predicate as it has been designed specifically to fit the SC+ Machine. The SC+ Blood Tubeset has been validated as part of the system and there is no impact on safety or performance.
- The maximum prime volume in the SC+ Blood Tubeset is less than that of the Predicate. This has no impact on performance and reduces the total amount of blood loss in the event the circuit needs to be discarded without returning blood back to the patient.

Comparison to the reference device demonstrated that the SC+ Blood tube set had lower hemolysis values.

None of these differences raise questions with regards to safety or effectiveness.

6.6 Performance Data

Extensive design verification and validation activities have been performed on the SC+ System. Performance testing, developed in accordance with appropriate FDA guidance documents and relevant standards, has been

performed on the SC+ System to support the determination of substantial equivalence, testing has included:

- Performance testing for dialysate quality, essential performance testing, and all the key functions/design features/components.
- Testing to confirm compliance with electrical and electromagnetic safety standards and performance of alarms and alerts.
- Performance testing for software and the touchscreen.
- Biocompatibility testing.
- Packaging and shelf life testing.
- Sterilization validation including pyrogenicity testing for the blood fluid path.
- Human factors testing.

6.7 Conclusion

The Performance Testing demonstrates that the SC+ Hemodialysis System (including the SC+ Blood Tubeset) meets all performance specifications and complies with applicable standards and FDA Guidance Documents. The SC+ Hemodialysis System is considered to be substantially equivalent to the predicate devices and the minor differences in the technological characteristics of the SC+ System and the predicate devices do not raise any new or different questions of safety or effectiveness.