August 12, 2021

Quanta Dialysis Technologies Ltd
Sam Drew
Risk and Regulatory Manager
1-3 Tything Road
Alcester, Warwickshire B49 6EU
UNITED KINGDOM

Re: K210661
Trade/Device Name: SC+ Hemodialysis Machine, SC+ Dialysate Cartridge, SC+ Blood Tubeset
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: Class II
Product Code: KDI, FJK
Dated: July 12, 2021
Received: July 13, 2021

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,

Carolyn Y. Neuland, Ph.D.
Assistant Division 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)*
K210661

Device Name
SC+ Hemodialysis Machine
SC+ Dialysate Cartridge
SC+ Blood Tubeset

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 considered competent in the use of the device.

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.

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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K210661 510(k) Summary
Date of preparation: 12th July 2021

510(k) Summary

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

1.1 Manufacturer

Quanta Dialysis Technologies Ltd
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B49 6EU,
United Kingdom

1.2 Contact

Sam Drew
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1.3 Device information

The SC+ Hemodialysis system comprises of the SC+ Hemodialysis Machine, the SC+ Dialysate Cartridge and the SC+ Blood Tubeset.

1.3.1 SC+ Machine & Dialysate Cartridge

1.3.1.1 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**

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

1.3.1.2 Predicate 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**
510(k) reference	**K193670**
Date of Clearance	**2020-12-23**

Table 2: SC+ device and Dialysate Cartridge predicate device information

1.3.2 SC+ Blood Tubeset

1.3.2.1 General Device Information

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 3: SC+ Blood Tubeset general device information

1.3.2.2 Predicate Device Information:

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**
510(k) reference	**K193670**
Date of Clearance	**2020-12-23**

Table 4: SC+ Blood Tubeset predicate device information

1.4 Device Description

The SC+ is a hemodialysis delivery system intended for acute and chronic dialysis therapy with or without ultrafiltration in an acute of chronic care facility. The system consists of the SC+ Machine, a single use disposable Dialysate Cartridge, and a sterile, single use, disposable Blood Tubeset.

1.4.1 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^{o}C 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.

1.5 Device Modifications

This 510(k) covers the following modifications:

- Addition of two-way wireless transmission capability for machine data
- Updated user workflows and interface for ease of use and streamlining

1.6 Indications for Use

1.6.1 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.

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

1.7 Technological Characteristics

1.7.1 Changed SC+ device vs SC+ device as cleared in K193670

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 (K193670). A summary of the similarities and differences is provided in the table below.

	Subject Device	Predicate Device
	SC+ (K210661)	SC+ (K193670)
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 5: Technological Characteristics of the SC+ Machine and predicate

Differences between the subject device and the predicate device:

- The subject device utilizes 3G/4G cellular communications to transmit machine data (non-clinical) to the Quanta Service Portal and download software updates (duplicating the predicate device's ethernet connectivity as cleared in K193670)
- The subject device has streamlined process with regards to air in venous line removal and priming

1.7.2 Changed SC+ Blood Tubeset vs SC+ Blood Tubeset device as cleared in K193670

The technological characteristics of the SC+ Blood Tubeset are considered to be equivalent to the predicate device, SC+ Blood Tubeset (K193670). A summary of the similarities and differences is provided in the table below.

	Subject Device	**Predicate Device**
	SC+ Blood Tubeset (K210661)	**SC+ Blood Tubeset (K193670)**
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	≤165ml
Needle configuration: Double needle	✓	✓

Table 6: Technological Characteristics of the SC+ Blood Tubeset and predicate

Differences between the subject device and the predicate device:

- The subject device includes a luer activated valve (needless valve/ air removal port) on the venous bloodline for streamlined air removal
- The saline spike preconnected to the arterial bloodline is replaced with a recirculation luer (this recirculation luer is a component as cleared in K193670)

1.8 Summary of Verification and Validation Activities

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:

- Performance testing to verify maintenance of the Electrical Safety and Electromagnetic Compatibility profiles
- Software verification
- Human Factors validation testing
- Biological safety testing

1.9 Conclusion

The modified devices are substantially equivalent to the predicate devices