November 1, 2024

Quanta Dialysis Technologies, Ltd.
Chris Rule
Director of Quality and Regulatory Affairs
The Woods, Haywood Road
Warwick, Warwick CV34 5AH
United Kingdom

Re: K242269
Trade/Device Name: SC+ Hemodialysis Device (SC-14269); Dialysate Cartridge (SC-14656); Blood Tube Set (SC-14651)
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: October 3, 2024
Received: October 4, 2024

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 (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
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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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K242269

Device Name

SC+ Hemodialysis Device (SC-14269);
Dialysate Cartridge (SC-14656);
Blood Tube Set (SC-14651)

Indications for Use *(Describe)*

SC+ Hemodialysis Device/ 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 clinician who is competent in the use of the device. The SC+ Hemodialysis System is also indicated for use in the home by trained patients in tandem with a trained care partner.

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 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.

1 510(k) Summary

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

Date prepared: October 28th, 2024

Manufacturer Details

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Device Information

1.3.1 SC+ Machine & Dialysate Cartridge

Trade Name	**SC+ Hemodialysis Device (SC-14269); Dialysate Cartridge (SC-14656); Blood Tube Set (SC-14651)**
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

1.3.2 SC+ Blood Tube Set

Trade Name	SC+ Blood Tubeset (SC-14651)
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

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.

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°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.

Device Modification

The differences contained within this submission regard the addition of home use to the SC+ Hemodialysis System's indications for use. The addition of home use to the indications expands both the locations and facilities in which treatment can be delivered (to encompass the home environment) and the potential users who can use the device (to include patients and caregivers).

Indications for Use

1.6.1 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 clinician who is competent in the use of the device. The SC+ Hemodialysis System is also indicated for use in the home by trained patients in tandem with a trained care partner.

1.6.2 SC+ Blood Tubeset

The SC+ Blood Tube Set 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.

Technological Characteristics

1.7.1 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)
The SC+ Hemodialysis System is also indicated for use in the home by trained patients in tandem with a trained care partner.	✓	✕
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.	✓	✓
Disinfection Method Heat: 80°C (Max)	✓	✓
Dialysate Temperature: Default Value 36.5 °C, Range: 35.0 – 37.5 °C	✓	✓
Dialysate Composition Control: 13.7mS/cm (low), 14.1mS/cm (high)	✓	✓
Dialysate Composition Protective System: 12mS/cm -16mS/cm	✓	✓
Dialysate Composition control: Conductivity	✓	✓
Bicarbonate Proportioning Default: 35 mEq/L (fixed), Minimum: 24 mEq/ L, Maximum: 40 mEq/ L	✓	✓
Blood flow rate Range: 50-450ml/min selectable	✓	✓
Accuracy: +/- 10%	✓	✓
Dialysate flow rate: Low Dialysis Fluid Flow = 300 mL/min ± 10%, High Dialysis Fluid Flow = 500 mL/min ± 10%	✓	✓
Ultrafiltration Range: 50 to 1000g/hr	✓	✓
Ultrafiltration mode: With dialysis fluid flow only	✓	✓
UF Accuracy: ± 400g/treatment, ± 100g/hr	✓	✓

Fluid Removal Volume: Minimum 0g, Maximum 4000g, Interval 10g	✓	✓
Venous Pressure Monitor: Minimum -100mmHg, Maximum 600mmHg, Interval 10 mmHg, Accuracy ± 20mmHg	✓	✓

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

The differences contained within this submission regard the addition of home use to the SC+ Hemodialysis System's indications for use. The addition of home use to the indications expands both the locations and facilities in which treatment can be delivered (to encompass the home environment) and the potential users who can use the device (to include patients and caregivers).

Pre-clinical and clinical data demonstrates that changed risk profile associated with the new use environment and user groups is acceptable with regards to safe and effective use.

The use of the device and the fundamental scientific concepts and technologies have not changed and the device performance remains identical to the predicate.

1.7.2 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	✓	✓
Indications: For use in the home environment	✓	✗
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

Summary of V&V

The addition of the Home Healthcare Environment prompts modifications to the testing for this type of device relative to the previously cleared product as identified in ANSI AAMI HA60601-1-11:2015, specifically that different physical and mechanical forces will be experienced within the home environment, due to the nature of the use environment.

Shock and vibration testing, with subsequent Essential performance and Basic Safety testing. A summary of the bench testing has been provided.

The addition of the Home Healthcare Environment also prompted a Human Factors Validation Study being conducted on lay users (patients and caregivers) in a simulated home environment. The following standards /FDA guidances were consulted in the study design: FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices (2016), IEC 62366-1:2015 (Application of Usability Engineering to Medical Devices), and IEC 62366-2:2016 (Guidance on the application of usability engineering to medical devices). The Human Factors Engineering documents have been provided.

Quanta has demonstrated the SC+ Machine is appropriate for its intended use through the use of hazard analysis in accordance with ISO 14971. Verification and validation of the user interface was completed through a series of simulated use Formative Studies and a comprehensive Human Factors Validation Study. In the Validation study, the participants were either trained or completed self-training and the results demonstrated that participants are able to safely and effectively use the SC+ Machine without making critical errors that could lead to a hazard. Therefore, SC+ Machine meets its intended use and is safe for the intended user population.

Quanta also performed original Pivotal Study and Actual Use Human Factors Study (HOME RUN, G200362) for the SC+ Hemodialysis System (SC+ Machine) to support the expansion of indication to Home-use. The safety and effectiveness of use of the SC+ Machine was evaluated to determine safety and effectiveness when Quanta SC+ is used in the self-care home environment compared to a hemodialysis facility.

The HOME RUN clinical trial was a prospective, multi-center (13 sites in US), open-label assessment of efficacy of and safety of SC+ Machine for Home Hemodialysis. Safety and effectiveness were assessed on the evaluable population (n = 32), which included all subjects who were enrolled in the study and successfully completed at least 75% of their dialysis treatments.

The primary effectiveness endpoint of this study was the mean standardized weekly Kt/V measured for dialysis delivered during the in-clinic and in-home stages of the study. The study demonstrated that the mean weekly standardized Kt/V was consistently above the target of 2.1 during all weeks of the in-clinic phase (≥2.3 in all phases C1-C8) and all weeks of the in-home phase (≥2.8 in all phases H1-H8).

The primary safety endpoints of this clinical investigation were the rate of AEs and pre-specified AEs per 100 treatments. The study was deemed successful as the AE rate per

100 treatments was not worse in the in-home phase compared to in the clinic. The AE rate per 100 treatments was low and acceptable as the upper bound of the 95% CI of the difference in the least squares mean AE rate was below 10%, at 2.73%. One death was reported that occurred during the clinical period and was unrelated to the device or procedure (i.e., infections and infestations: COVID-19).

An independent safety and clinical ethics committee (SCEC) was created, chartered and maintained whilst any AEs were reported or subjects were receiving study treatment to oversee trial safety, as per the study protocol. The SCEC comprised nephrologists with experience of hemodialysis, one of which had significant experience in home hemodialysis. The SCEC were blinded to whether AEs occurred in the in-clinic or in-home phase. The committee also had the authority to recommend that the trial continue with no changes, continue with changes to the protocol, or be suspended. For this study, the SCEC concluded that no serious harm AEs related to use error were identified and no recommendations were made that would indicate that the use of the Quanta SC+ hemodialysis system is a problem.

Results of the HOME RUN Study demonstrate SC+ Machine safely and effectively delivers treatment to subjects in both an in-clinic and in-home setting. There is no additional risks or safety concerns when using this device in a home setting with a care partner providing device competency has been achieved.

In summary, the clinical data provided in this submission support expansion of the general system indications to include specific indications for home-use. The data included in this submission demonstrate substantial equivalence to the predicate device listed above.

The nonclinical and clinical testing supplied as part of this submission demonstrate that the change in indications to include home healthcare environments is substantially equivalent with regards to safety and effectiveness when compared to the predicate devices.

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.