January 3, 2024

Q for Plastic Industries
% Abdel Halim
President
Global Quality and Regulatory Services
10 Scenic Way
Monroe, New Jersey 08831

Re: K231707
Trade/Device Name: ResQ Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: December 3, 2023
Received: December 4, 2023

Dear Abdel Halim:

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.

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,

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,

and Human Factors
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231707

Device Name
ResQ Administration Set

Indications for Use *(Describe)*
ResQ Administration set is intended to administer fluids from a container to a patient's venous system through a needle or catheter inserted into the vein. The set is a sterile, disposable for a single use. The ResQ Administration Set should be used no more frequently than at 96-hour intervals. It can be used on patients of all age groups under the supervision of a qualified physicians or nurses in hospital or clinical settings.

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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K231707 - 510(k) Summary

Date:	Dec. 22, 2023
Submitter (Owner):	**Islam Nazeih Mohamed Ali** Chief Executive Officer **Islam Nazeih Mohamed Ali and Partner** Land plot #25,27 first industrial zone, Badr city ,11829Cairo, Egypt Phone: +20 1146626663 E-mail ID: i.aly@qmedicaldevices.com
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Device Trade Name:	ResQ Administration Set
Common name:	Intravascular administration Set
Regulation Number:	21 CFR 880.5440
Regulation classification Description:	Intravascular Administration Set
Review Panel:	General Hospital
Device Class:	Class II
Product Code:	FPA
Predicate Device:	510(k) Number: K112204 Product Name: KDL Disposable Infusion Set Manufacturer: Shanghai Kindly Enterprise Development Group Co., Ltd.

Device Description

ResQ Administration set is a single use, gravity feed, sterile device sterilized with Ethylene Oxide Gas. ResQ Administration set is intended to administer fluids from a container to a patient's venous system through a needle or catheter inserted into the vein. The set is a sterile, disposable for a single use. The ResQ Administration Set should be used no more frequently than at 96-hour intervals. It can be used on patients of all age groups under the supervision of a qualified physicians or nurses in hospital or clinical settings.

ResQ Administration set is compatible with various cannula or catheters models and can be used for most low viscosity fluids or medications.

The proposed device consists of protective cap, air filtration membrane, closure-piercing device, drip chamber, medicine fluid filter, roller clamp, tubing, flow regulator, injection sites (needle access – needleless access), in-line filter &two-part luer lock connector.

The protective cap is intended to maintain sterility and to protect the closure piercing device that used to pierce the container, the drip chamber is transparent so that the user can observe the dropping condition of the medical solution, it has an air filtration membrane which can filter the air into the container and an air-inlet set which can control the air into the container and a medicine fluid filter which can filter the medical solution, the roller clamp is used to control the flow of the medicine solution, the tubing is used to connect various components, the flow regulator is used to adjust the flow rate from zero to maximum, there are two injection sites one is needleless and the other is needle access, which are used to inject solution into the tubing, the in-line filter used for retention of particles, bacteria and fungi, also it used for elimination of the air, two-part luer lock connector is used to connect the infusion needle or catheter with the tubing.

- It is single use device, sterilized by EO sterilization.
- Environment of Use: healthcare facility/hospital

Indications for Use

ResQ Administration set is intended to administer fluids from a container to a patient's venous system through a needle or catheter inserted into the vein. The set is a sterile, disposable for a single use. The ResQ Administration Set should be used no more frequently than at 96-hour intervals. It can be used on patients of all age groups under the supervision of a qualified physicians or nurses in hospital or clinical settings.

Contraindications

- Some patients have anatomy that poses a risk for fluid extravasation or inadequate flow and peripheral IVs should be avoided in these situations.
  - Include extremities that have massive edema, burns or injury.
  - For the patient with severe abdominal trauma, it is preferable to start the IV in an upper extremity because of the potential for injury to vessels between the lower extremities and the heart.
  - For the patient with cellulitis of an extremity, the area of infection should be avoided when starting an IV because of the risk of inoculating the circulation with bacteria. As well, extremities on the side of a mastectomy or that have an indwelling fistula should be avoided because of concerns about adequate flow.
  - Administration of highly viscous fluids like human albumin, Dextrans, Etherified Starch, Plasma Protein Fraction & Gelatin.
- Blood transfusion: the device isn’t designed to be used for blood transfusion.

Working Principle

Closure piercing device inserted into ResQ Administration set. Container and roller clamp is opened and permitted chamber to fill to required level, squeeze drip chamber to fill half full and open roller clamp again to refill to required level. Close roller clamp and make sure there is solution in the drip chamber that way it enables precise volume and slow Administration of infusion or injectable medicine.

A micro regulator is integrated into ResQ Administration set for precise flow control to regulate the flow of IV fluid from an infusion set into an IV catheter.

A filter serves as security barrier, its membrane has symmetrical diameter ensuring no medium to fall off or deform with the function of removing contaminations including bacteria, fungi and endotoxins from the tubing, it guarantees high-precision filtration.

Comparison to Predicate Device

One predicate device is selected in this submission for ResQ Administration set. Predicate device: KDL Disposable Infusion Set and the details of the substantial equivalence between the subject device and predicate device is explained below:

Table 1: Comparison to Predicate Devices

Comparable Properties	Subject Device (K231707)	Predicate Device (K112204)	Comparison Results
Device Name	ResQ Administration set	KDL Disposable Infusion Set	N/A
Regulation Number	21 CFR 880.5440	21 CFR 880.5440	Identical
Product Code	FPA	FPA	Identical
Product Class	II	II	Identical
Intended Use / Indications for Use	The device is intended to administer fluids from a container to a patient's venous system through a needle or catheter inserted into the vein. The set is a sterile, disposable for a single use. The ResQ Administration Set should be used no more frequently than at 96-hour intervals. It can be used on patients of all age groups under the supervision of a qualified physicians or nurses in hospital or clinical settings.	Disposable Infusion Set is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein. It can be used on patients of all age groups under the supervision of a qualified physician or health care professionals in hospital or clinical settings.	Different Only we mentioned in the indication for use of our device that it should be used no more frequently than at 96-hour intervals And we state that the solution will be administered in to the patients venous system and the predicate states that it is administered into the patients vascular system
Mode of Fluid Delivery	Gravity	Gravity	Identical

Comparable Properties	Subject Device (K231707)		Predicate Device (K112204)		Comparison Results
Single-Use	Yes		Yes		Identical
Prescription only	Yes		Yes		Identical
Disposable	Yes		Yes		Identical
Configuration and material	Configuration	material	Configuration	material	Different 1
	Protective Cap of Closure-piercing Device (Spike)	HDPE	Protective Cap of Closure-piercing Device	Unknown	
	Closure-piercing Device (Spike)	ABS	Closure-piercing Device		
	Air Vent	PVC	Air Vent		
	Drip Chamber	PVC	Drip Chamber		
	Fluid Filter	ABS	Fluid Filter		
	Flexible Tube	PVC	Flexible Tube		
	Roller Clamp	HDPE	Roller Clamp		
	needleless port	Synthetic Silicone	needleless port		
	Y-Injection site	Synthetic Silicone	Y-Injection site		
	Luer Lock Connector	PVC	Luer Lock Connector		
	Protector Cap of	HDPE	Protector Cap of		
	Luer Lock Connector	Luer Lock Connector			
	In-Line Filter	PVC	In-Line Filter		
	Flow regulator	ABS	Flow regulator		
	—	—	Infusion needle		
Tubing Diameter	4mm		3.9 mm		Different 3
Filter Characteristics	0.2 μm for in line filter and 15μm for fluid filter		0.2 μm for in line filter and 15μmfor fluid filter		Identical
Infusion Set Performance	Conform with ISO 8536-4:2019		Conform with ISO 8536-4:2010		Identical
Flow rate of regulator	5 to 250 ml/hour		20 to 250 ml/hour		Different 4
Sterility	ETO sterilization		ETO sterilization		Identical
Biocompatibility	ISO 10993-1 ISO 10993-4 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-23		Conform with ISO 10993 series standards		Identical

Comparable Properties	Subject Device (K231707)	Predicate Device (K112204)	Comparison Results
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801	Identical

Note 1	The subject device Configurations and materials are not contained needle where the KDL Disposable infusion set configuration with infusion needle. The performance and biocompatibility testing on the subject device demonstrate substantial equivalence. All the performance testing of the device as mentioned below in table 2 in this summary and they were done as per product standard and FDA guidance for this device indicate that the subject device testing results were all accepted as per acceptance criteria for the tests and the biocompatibility testing as mentioned below in table 3 in this summary also done as per ISO10993-1 and all the results was accepted for the subject device and their testing results was accepted as per testing ISO standard requirements.
Note 2	The subject device configuration and material not contain needle but contain the male luer lock with its cover which comply with ISO 80369 where the KDL Disposable infusion set configuration with infusion needle so it complies with ISO 594-1, ISO 594-2. The performance testing on the subject device demonstrates substantial equivalence without raising any new questions of safety and effectiveness.
Note 3	The Subject device tube diameter is 4mm. The performance testing on the subject device demonstrates substantial equivalence without raising any new questions of safety and effectiveness. We did for the subject device flow rate testing and tensile strength testing as per (ISO 8536-4 Sixth edition 2019-09 Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed.) and the results were accepted as per acceptance criteria for the test and the tube diameter was not raise any new question for safety or performance of the device
Note 4	The subject device Flow rate limit from 5 to 250mm, the performance testing on the subject device demonstrates substantial equivalence without raising any new questions of safety and effectiveness. As the flow rate of the predicate device limit is from 20 to 250 and the subject device limit is from 5 to 250 so all the predicate device range is within the range of the subject device and we did the flow rate testing for the subject device and all results were accepted as per test acceptance criteria.

Performance Data

The following tests according to the identified standards / guidance were conducted on ResQ Administration set to verify the performance of the device:

Table 2: Bench Testing of ResQ Administration set

Inner Diameter of PVC Tube**:** 3.0 ± 0.1mm as per ISO 8536-4:2019
Outer Diameter of PVC Tube**:** 4.1 ± 0.1 mm as per ISO 8536-4:2019

S. No.	Test Description	Standard/Guideline
1.	Leakage test of Infusion set.	ISO 8536-4 Sixth edition 2019-09 Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed.
2.	Tensile strength.	
3.	Leakage of the IV injection site.	
4.	Efficiency of the IV set fluid filter.	
5.	Particulate contamination test.	
6.	Test for titration acidity or alkalinity	
7.	Test for Reducing (oxidizing matters).	
8.	Test for non- volatile residue.	
9.	UV Absorption of extract solution.	
10.	Determination of Fluid Flow Rate for IV Administration Set with Integral Air Inlet Device.	
11.	Flow rate for graduate flow regulator.	ISO 8536-13 First edition 2016-10 Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact.
12.	Determination of Graduated Flow Regulator Leakage Test.	
13.	Test for falling drop positive pressure liquid leakage for male luer connector.	ISO 80369-7 Second edition 2021-05 Small- bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications.
14.	Test for Resistance to overriding for male luer connector.	
15.	Test for Resistance from separation from axial load for male luer connector.	ISO 80369-20 First edition 2015-05-15 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods.
16.	Test for Resistance to overriding for needle free connector with LAV.	ISO 80369-7 Second edition 2021-05 Small- bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications.
17.	Test for Resistance from separation from axial load for Luer Activated Valve (LAV) of Needle Free Connector.	

18.	Resistance to separation from unscrewing for needle free.	ISO 80369-20 First edition 2015-05-15 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods. ANSI AAMI CN27:2021 General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications.
19.	Positive Pressure Liquid Leakage (activated) for Needle Free.	
20.	Sub atmospheric pressure air leakage (activated) for Needle Free.	
21.	Test for IPA Exposure for Needle Free.	ISO 1135-4:2015 Transfusion equipment for medical use – Part 4: Transfusion sets for single use, gravity feed.
22.	Test for Priming Volume for Needle Free.	
23.	Test for Residual Volume for Needle Free.	
24.	Test Method of Flow rate for needle free.	
25.	Test for Backpressure (unactivated) for Needle Free.	
26.	Test for Displacement for Needle Free.	
27.	Test for sub atmospheric pressure air leakage (Unactivated) for Needle Free.	
28.	Test of Number of Activations for Needle free.	
29.	Test for Infusate compatibility.	
30.	microbial ingress of check valve, needle less port and Y- injection port	
31.	Needleless Access Port Activation Time Test.	ISO 1135-4:2015 Transfusion equipment for medical use – Part 4: Transfusion sets for single use, gravity feed.
32.	Needleless Access Port Leakage Test During Aspiration. There are 6 models of our device 2 ،of which containing 1 check valve only, one model containing no any check valve and the other 3 models containing 3 check valves The microbial ingress test is concerned with only the check valves (injection ports and needless ports) So, we should do the test on the worst case model that contain 2 check valves We performed the microbial ingress test for the test article (IVQ49) as we consider this model as the worst case model (in this test) which contains 2 check valves (1 injection port, and one needless port) also it contains the most number of device other components.	
33.	Needleless Access Port Leakage Test.	

34.	Test for air/water leakage for infusion set in line filter.	ISO 8536-11 Second Edition 2015-06-15 Infusion Equipment for Medical Use - Part 11: Infusion Filters for Single Use with Pressure Infusion Equipment.
35.	Ethylene oxide sterilization validation and routine control.	ISO 11135:2014 Sterilization of health- care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)].
36.	Shelf-life study by accelerated aging studies.	ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
37.	Device packaging integrity testing (Dye Penetration Test).	ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.
38.	Device packaging integrity testing (Bubble emission).	ASTM D3078-02 (Reapproved 2013) Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission.
39.	Device packaging integrity testing.	ASTM F1140/F1140M- 13 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.
40.	Bio-burden Of Finished Product.	ISO 11737-1:2018.
41.	Sterility Test for Sterile Product.	-USP 41 chapter 71.
42.	Test Method of Pyrogen Test.	- ISO 11737-2: 2019.

Based on the tests performed and information provided on predicate devices, it can be concluded that the subject device is substantially equivalent to the predicate devices and raises no new issues of safety and performance.

Biocompatibility Data

Product name: ResQ Administration set.

Category: external communication device.

Contact: blood path indirect.

Contact duration: prolonged (24 h to 30 days)

And are under category of external communication device blood path indirect to ensure safety of ResQ Administration set during use in patients, testing and risk assessment as per ISO 10993-1 were performed. Testing included the following assessments:

Table 3: Biological Evaluation of ResQ Administration set

S. No.	Test Name	Reference guidance document / standard
1.	Cytotoxicity	ISO 10993-5:2009
2.	Sensitization guinea pig maximization test	ISO 10993-10:2021
3.	(GPMT)	ISO 10993-23:2021
4.	Irritation	ISO 10993-11:2017
5.	Acute toxicity	ISO 10993-11:2017
6.	Subacute toxicity	ISO 10993-4:2017
7.	Hemocompatibility	ISO 10993-4:2017
8.	Hemolysis	ISO 10993-11:2017

Testing results and risk assessment demonstrated that materials used in the construction of ResQ Administration set were safe and elicited no reactions in test animals.

Clinical Performance Summary

Not applicable. No clinical tests were conducted for this submission.

Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The ResQ Administration set manufactured by Q for Plastic Industries is substantially equivalent to the KDL Disposable Infusion Set and is as safe and effective when used as intended.