Eitan Medical Ltd.
% Rhona Shanker
President
Z & B Enterprises, Inc.
12154 Darnestown Road, #236
Gaithersburg, Maryland 20878

March 10, 2023

Re: K213744
Trade/Device Name: Avoset Infusion Pump System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, MRZ, FPA
Dated: February 14, 2023
Received: February 14, 2023

Dear Rhona Shanker:

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,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
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)*
K213744

Device Name
Avoset Infusion Pump

Indications for Use *(Describe)*

Intended use:
The Avoset Infusion Pump is a single-channel, volumetric infusion pump. Medication is delivered at continuous rate, and/or with an intermittent bolus, and/or with a patient bolus and/or with taper.
Indication of use:
Routes: Parenteral (intra-arterial, intra-venous, subcutaneous, perineural, epidural)
and enteral infusions
Fluids: IV medication (including fluids), Total Parenteral Nutrition (TPN), enteral medication and nutrition, lipids, epidural medication.
Program Types (specific uses): The pump delivers in one of four program types: a continuous rate of infusion, and/or an intermittent bolus, and/or with patient-controlled intermittent doses, and/or with tapering.
Patient Population: Pediatric: infants, children, and adolescents and adult patients.
Intended Environments. Intended to be used in clinical environment and ambulatory environment including, home, plane and ground transportation.
Users: licensed health care professional and lay users
The dedicated Administration Sets for the Avoset Infusion Pump are intended for single-patient use and single-use only.
Set configurations are: (i) Enteral; (ii) Epidural and (iii) General purpose for the balance of the routes: intra-arterial, intra-venous, subcutaneous, perineural.
The Avoset Programming Tool is intended to be used with a computer to create a treatment-based protocol that is loaded onto the pump. The programming tool is intended for use by professional users.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K213744 510(k) Summary

Owner/Submitter	Eitan Medical Ltd. 29 Yad Haruzim St. Netanya 4250529 ISRAEL Ph: +972-73-2388888 Fax: +972-73-2388800
Contact Person	Rhona Shanker FDA Regulatory Consultant to Eitan Medical Ltd Ph: 301-251-9570 Email: rhonashanker07@verizon.net
Trade Name	Avoset Infusion Pump
Common Name	Infusion Pump
Classification Name	Infusion Pump 21 CFR 880.5725 Product Codes: FRN - Infusion pump MRZ - Infusion pump accessories FPA - Administration Sets (21 CFR 880.5440) Class II
Predicate Device For Infusion pump	CADD-Solis system (pump and PC Tool) cleared under K170982
Predicate Device for Administration sets	(K192860) Sapphire administration sets
Date of Preparation	8 March 2023

Device Description

The Avoset Infusion system (pump and accessories) covered by this submission is the Avoset infusion pump, an ambulatory pump intended for controlled infusion at rates between 0.1-300 mL/h at a continuous rate, and/or with an intermittent bolus, and/or with a patient bolus and/or with taper, in the hospital and home environments for pediatric and adult patients.

The Avoset infusion pump weighs 365 grams, has 89 parts, and allows infusion from (i) bags; (ii) syringes; and (iii) non collapsible medication reservoirs.

The device also contains an optional module (referred to as "Insight Tool"). The module receives data from the pump and uses it for (i) fleet management and (ii) treatment monitoring applications to ensure patient has completed the treatment. This module does not impact or pass data into the pump.

The dedicated Avoset Administration Sets are sterile (apart of the Enteral sets) and intended for single-patient use and single-use only.

Intended and Indications for Use

Intended Use
The Avoset Infusion Pump is a single-channel, volumetric infusion pump. Medication is delivered at continuous rate, and/or with an intermittent bolus, and/or with a patient bolus and/or with taper.
Indication for use
Routes: Parenteral (intra-arterial, intra-venous, subcutaneous, perineural, epidural) and enteral infusions
Fluids: IV medication (including fluids), Total Parenteral Nutrition (TPN), enteral medication and nutrition, lipids, epidural medication.
Program Types (specific users): The pump delivers in one of four program types: a continuous rate of infusion, and/or an intermittent bolus, and/or with patient-controlled intermittent doses, and/or with tapering
Patient Population: Pediatric: infants, children, adolescents and adult patients
Intended Environments: Intended to be used in clinical environment and ambulatory environment including, home, plane and ground transportation.
Users: licensed health care professional and lay users
The dedicated Administration Sets for the Avoset Infusion Pump are intended for single-patient use and single-use only.
Set configurations are: (i) Enteral; (ii) Epidural and (iii) General purpose for the balance of the routes: intra-arterial, intra-venous, subcutaneous, perineural.
The Avoset Programming Tool: is intended to be used with a computer to create a treatment-based protocol that is loaded onto the pump. The programming tool is intended for use by professional users.

Pump Substantial Equivalence Discussion summary

The table below includes a comparison of the indications for use between the new device and that of the predicate:

Characteristic	**Subject Device - Avoset Infusion Pump**	**CADD®-Solis Infusion Pump, Model 2110 (K170982)**
Indications for Use	Intended Use The Avoset Infusion Pump is a single-channel, volumetric infusion pump. Medication is delivered at continuous rate, and/or with an intermittent bolus, and/or with a patient bolus and/or with taper. Indication for use Routes: Parenteral (intra-arterial, intra-venous, subcutaneous, perineural, epidural) and enteral infusions	Intended use Intended to be used for patient care for adult and pediatric patients in multiple clinical care areas, including but not limited to post-operative, trauma, critical care, oncology, and labor and delivery. The pump can be programmed with a protocol configuration consisting of a therapy, qualifier, and drug. Medication is delivered at a constant rate, and/or with an

	Fluids: IV medication (including fluids), Total Parenteral Nutrition (TPN), enteral medication and nutrition, lipids, epidural medication. Program Types (specific users): The pump delivers in one of four program types: a continuous rate of infusion, and/or an intermittent bolus, and/or with patient-controlled intermittent doses, and/or with tapering Patient Population: Pediatric: infants, children, adolescents and adult patients Intended Environments: Intended to be used in clinical environment and ambulatory environment including, home, plane and ground transportation. Users: licensed health care professional and lay users The dedicated Administration Sets for the Avoset Infusion Pump are intended for single-patient use and single-use only. Set configurations are: (i) Enteral; (ii) Epidural and (iii) General purpose for the balance of the routes: intra-arterial, intra-venous, subcutaneous, perineural. The Avoset Programming Tool: is intended to be used with a computer to create a treatment-based protocol that is loaded onto the pump. The programming tool is intended for use by professional users.	intermittent bolus, and/or with a patient dose. <u>Indication for use</u> Indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal, in close proximity to nerves, into an intraoperative site (soft tissue, body cavity/surgical wound site), epidural space or subarachnoid space. The pump is intended for therapies that require a continuous rate of infusion, and/or an intermittent bolus, and/or with patient-controlled demand doses
Prescription or over the counter	Prescription	Prescription
Intended population	Pediatric (infants, children, and adolescents) and adult patients.	Pediatric and adult patients.
Environment of Use	Clinical environment and ambulatory environment including home, plane and ground transportation	Multiple clinical care areas, including but not limited to post-operative, trauma, critical care, oncology, and labor and delivery

<u>Discussions of differences in Indications for Use statement</u>

The Avoset pump has two additions to the Indications for Use statement:

- **Enteral Route**: The enteral delivery route was added.
- **Taper Delivery profile**: This delivery mode was added to allow for infusion that require this mode.

<u>Discussion of differences in the intended population</u>

The target population includes adults and pediatrics excluding neonates. The predicate device does not exclude neonates.

Discussion of differences in the Environment of Use

The Avoset pump includes use in ambulatory environments: The predicate device is limited to use in clinical environments.

Conclusion: The CADD is the appropriate predicate device with respect to the indications/ intended use, despite of the differences identified above.

Pump system Technological Characteristics

The table below includes a comparison of the technological characteristics between the new pump system and those of the predicate pump:

	Description	**Subject Device - Avoset Infusion Pump**	**CADD®-Solis Infusion Pump, Model 2110 (K170982)**	**Comments**
	Pump			
Design	**Pumping mechanism**	Microprocessor controlled linear peristaltic pumping mechanism (Single channel volumetric)	Microprocessor controlled linear peristaltic pumping mechanism (Single channel volumetric)	Identical
	Dimensions	Approximately 424 cm^3 (96 mm x 96 mm x 46 mm); Approximately 400 grams	Approximately 500 cm^3 (40mm x 101mm X 127mm); Approximately 600 grams	Similar dimensions and weight
	Motor	DC motor operated by internal batteries and controlled by SW	DC motor operated by internal batteries and controlled by SW	Identical
	Accuracy	± 5% (including boluses) under most conditions. Additional details provided in the labeling.	6%	Supported through performance testing
	Flow rate	0.1-300 mL/h	0.1-500 mL/h	Within predicate range
	VTBI capacity range	0- 9,999mL	0- 9,999mL	Identical
	Occlusion detection pressure	Upstream: fixed (pre-set in the pump; no option for user to modify) threshold	Upstream: fixed (pre-set in the pump; no option for user to modify) threshold	Identical
		Downstream: 0.5 - 1.6 Bar	0.62 - 1.68 bar	Tighter range than the predicate

	Description	Subject Device - Avoset Infusion Pump	CADD®-Solis Infusion Pump, Model 2110 (K170982)	Comments
	Air detection	100 µL minimal detection level	150 µL	Tighter spec than predicate
	Air off	Optional mode	Optional mode	Identical
	Alarms	Low Battery, battery depletion, battery extraction, pump unattended, action incomplete, cassette misplaced, key stuck, upstream occlusion, downstream occlusion, infusion complete, add bag, air in line, HW/mechanical/SW failures. Alarms comply with IEC 60601-1-8	Low Battery, battery depletion, battery extraction, pump unattended, action incomplete, cassette misplaced, key stuck, upstream occlusion, downstream occlusion, infusion complete, add bag, air in line, HW/mechanical/SW failures. Alarms comply with IEC 60601-1-8	Identical
Material	**Administration sets**	The fluid path of the administration sets is biocompatible	The fluid path of the administration sets is biocompatible	Identical
Energy source	**Powered by**	Rechargeable: Duracell DX1500 Alkaline: Duracell MN1500 (a.k.a. coppertop)	Rechargeable battery pack or AC adaptor	Within predicate power options
Other device features	**UI**	LCD screen, keypad user interface	LCD screen, keypad user interface	Identical
	Reservoir	Syringe (5-60mL) (in addition to infusion bag and a dedicated cartridge)	Infusion bag, dedicated cartridge, no syringe	See comment 2
	Connectivity	BLE and NFC	Wi-Fi	See comment 3
Pump Service life	**Service life**	7 years	5 years	Difference supported through performance testing
Pump Altitude operation range	**Altitude operation range**	50 kPa to 106 kPa [equivalent to altitude of -381 m to 6096 m (-1210 ft to 20000 ft)]	70 kPa to 106 kPa	Difference supported through performance testing
Use environment	**Ambulatory**	Ambulatory (home, plane, and ground transportation)	Ambulatory	Difference supported through performance testing. See comment 1

	Description	Subject Device - Avoset Infusion Pump	CADD®-Solis Infusion Pump, Model 2110 (K170982)	Comments
PC Tool				
Intended Use	Intended Use	The Avoset Programming Tool is intended to be used with a computer to create a treatment-based protocol that is loaded onto the pump. The programming tool is intended for use by professional users.	Allows the use of a computer to create therapy-based protocol libraries to be used with the CADD®-Solis Infusion Pump.	See comment 4
Design	Treatment data transfer	Allow the transfer of treatment data to the pump: Delivery profile, Drug, rate, VTBI, PCA dose, dose lockout, maximum dose, hard limits for VTBI, rate and KVO, weight-based units, concentration, air detection threshold, occlusion threshold, alarm volume, delayed start.	Allow the transfer of treatment data to the pump: Delivery profile, Drug, rate, VTBI, PCA dose, dose lockout, maximum dose, hard limits for VTBI, rate and KVO, weight-based units, concentration, air detection threshold, occlusion threshold, alarm volume, delayed start.	Identical
	Number of treatments	Only one treatment is sent to the pump at a time	Several treatments are sent ("therapy-based…. libraries") to the pump from which a single treatment is manually selected on the pump by the user	See comment 4
Accessories				
Design	Accessory	Cassette lock	Lockbox	Identical
Design	Accessory	Avoset Cradle	Pole mount adapter	Identical

Discussions of differences in technological characteristics

Comment 1

These uses are supported by compliance with:

- RTCA DO-160 section 20 (category R): for plane environment
- IEC 60601-1-11: for ground environment

demonstrating safe and effective operation also under plane environment

Comment 2

The Avoset pump has the ability to draw from a syringe. This capability does not raise new questions of safety and/or effectiveness since the Avoset's pumping mechanism is such that accuracy is not impacted by the source from which medication is drawn.

Comment 3

The Avoset pump wireless communication technology is BLE and NFC (opposed to Wi-Fi in the predicate). Avoset wireless complies with FCC, EMC (IEC 60601-1-2) and coexistence (as required) according to FDA guidance. Respective technologies are well established and

comparable. The connection does not allow for remote programming or control of the connected pump.

Comment 4

Avoset's PC (software) tool is within the scope of the predicate's software tool Intended and Indication for use.

Both tools allow the programing and transferring of treatment information from the tool to the pump. The Avoset tool sends a single treatment ("a treatment") while the predicate can send more than one treatment to the pump.

Conclusion: The technological differences do not raise new questions of safety and effectiveness

Administration Sets Substantial Equivalence Discussion summary

Set configurations are: (i) Enteral; (ii) Epidural and (iii) General purpose for the balance of the routes: intra-arterial, intra-venous, subcutaneous, perineural.

Avoset has identified as the predicate the Sapphire's Administrations sets (K192860). Below is a discussion of how the two compare with respect to the Intended use/Indications for use and the technological characteristics.

Intended use & Indication for use:

Characteristic	**Subject Device - Avoset Infusion Pump**	**Sapphire's Administrations sets (K192860)**
Indications for Use	Intended Use The Avoset Infusion Pump is a single-channel, volumetric infusion pump. Medication is delivered at continuous rate, and/or with an intermittent bolus, and/or with a patient bolus and/or with taper. Indication for use Routes: Parenteral (intra-arterial, intra-venous, subcutaneous, perineural, epidural) and enteral infusions Fluids: IV medication (including fluids), Total Parenteral Nutrition (TPN), enteral medication and nutrition, lipids, epidural medication. Program Types (specific users): The pump delivers in one of four program types: a continuous rate of infusion, and/or an intermittent bolus, and/or with patient-controlled intermittent doses, and/or with tapering Patient Population: Pediatric: infants, children, adolescents and adult patients Intended Environments: Intended to be used in clinical environment and ambulatory	The Sapphire Infusion pump is intended for controlled delivery through intravascular, subcutaneous, intra-arterial, perineural and epidural routes. The pump is designed to deliver saline, Total Parenteral Nutrition (TPN),lipids, IV medication, perineural medication, epidural medication, blood and blood products. The Sapphire Infusion pump includes the following infusion modes for all intended uses: Continuous, Intermittent, TPN, PCA, Multi-step, and Epidural. It is intended to be used in the following environments of use: clinical, ambulatory, pre-hospital medical air and ground transportation and home. The pump is intended to be used by both licensed health care professionals and by lay users. The Sapphire and the administration sets are indicated for use by both adult and pediatric

	environment including, home, plane and ground transportation. Users: licensed health care professional and lay users The dedicated Administration Sets for the Avoset Infusion Pump are intended for single-patient use and single-use only. Set configurations are: (i) Enteral; (ii) Epidural and (iii) General purpose for the balance of the routes: intra-arterial, intra-venous, subcutaneous, perineural. The Avoset Programming Tool: is intended to be used with a computer to create a treatment-based protocol that is loaded onto the pump. The programming tool is intended for use by professional users.	populations. The dedicated Q Core administration sets for the Sapphire pump are intended for single-patient use and single-use only.

Discussions of differences in Indications for Use statement

The indications for use statement for the subject device is identical to the predicate device.

Technology characteristics:

As shown in the table below, all technological characteristics listed in the table below are the same except for the design of Avoset's dedicated cartridge. (V&V demonstrates that this difference does not have an impact on safety or effectiveness):

	Description	**Subject Device - Avoset Infusion Pump**	**Sapphire's Administrations sets (K192860)**	**Comments**
Design	Used with	Sets intended for use with only the specified infusion pump to allow peristaltic flow (by the pump pressing on the cassette tube)	Sets intended for use with only the specified infusion pump to allow peristaltic flow (by the pump pressing on the cassette tube)	Identical
	Interaction with the pump	Each administration sets includes a dedicated administration cassette responsible for pump interaction	Each administration sets includes a dedicated administration cassette responsible for pump interaction	Identical
	Free flow prevention	Anti-Free Flow Valve in the administration cassette	Anti-Free Flow Valve in the administration cassette	Identical
	Length	1.7-3.2m	2.1-3m	Difference supported through performance testing (Slightly wider

	Description	Subject Device - Avoset Infusion Pump	Sapphire's Administrations sets (K192860)	Comments
				range than predicate)
	Priming volume	1-28mL	3-30mL	Within predicates range
	Components on the infusion line	• Filters, • Drip chamber • Slide clamps • Roller clamp • Spike • Needless y site • Connectors	• Filters, • Drip chamber • Slide clamps • Roller clamp • Spike • Needless y site • Connectors	Identical
	Different configurations of the Sets are available, depending upon the required use	• Different configurations are available with the different component options as above • **Optional Cartridge (for 100mL bag)**	• Different configurations are available with the different component options as above	Difference supported through performance testing (The last set component (bolded) has the same administration cassette & functionality and has no additional materials).
Sterility	Method	EtO	EtO	Identical
	SAL	10^{-6}	10^{-6}	Identical
	Use frequency	Single use	Single use	Identical
	Shelf life	2.3 years	5	within the predicate range
Material	Not containing	Non-DEHP, latex free and non-pyrogenic	Non-DEHP, latex free and non-pyrogenic	Identical
	Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Identical
	Materials	• PVC • ABS • Acrylic • Polyethylene • Polyethersulfone • Polytetrafluoroethylene • Silicone • Polypropylene • Polyamide • **Polycarbonate** • **Polyurethane** • **Rigid PVC** • **TPE**	• PVC • ABS • Acrylic • Polyethylene • Polyethersulfone • Polytetrafluoroethylene • Silicone • Polypropylene • Polyamide	Difference supported through performance testing (last additional 4 bolded materials)

Conclusion: The respective administration sets have the same intended & indication for use and technological characteristics and thus the Sapphire sets are appropriate predicates.

Performance Testing

The following bench testing was performed and reviewed to support the substantial equivalence of the subject device:

Software	Software verification and validation per the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005) for a Major Level of Concern and IEC62304:2006/AMD 2015
Electrical safety	Electrical Safety per IEC 60601-1; 2012
EMC	EMC testing per IEC 60601-1-2; 2014
Home use	Per IEC 60601-1-11; 2015
Alarms	Alarms per IEC 60601-1-8; 2012
Device Performance	• FDA Guidance "Infusion Pumps Total Product Life Cycle" • Accuracy testing under anticipated environments of use and routes • Performance per ISO 8536-4, -8, -9, -10, -11 • Administration sets performance testing per ISO 80369-6:2016
Biocompatibility	ISO 10993-1 (Administration sets)
Sterility	Validation per ISO 11135
Human Factors	Human factors studies per the FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016). The human factors studies were conducted with the intended user population, use environment, and use scenarios to simulate clinical conditions. Results of the human factors testing demonstrate validation of the device per the intended use.
Cybersecurity	Cybersecurity was evaluated per the FDA Guidance Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff, (Draft guidance, October, 2018). Postmarket Management of Cybersecurity in Medical Devices – Guidance for Industry and FDA Staff (2016) and AAMI TIR57 – Principles for Medical Device Security (2016) Specifically, addressing the following areas: Identify and Protect, Detect, Response and Recovery
Reprocessing/Cleaning	Validation per the FDA Guidance for Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (March 17, 2015) confirmed cleaning and disinfection instruction provided in instructions for use
Shipping	Per ASTM D4169-16

The testing conducted demonstrates that the Avoset Infusion pump system meets its design requirements and is substantially equivalent to the cleared CADD Solis system. Therefore, the Avoset Infusion Pump system that is the subject of this submission is substantially equivalent to the identified predicates.

Conclusion

The Avoset Infusion system (pump, sets and accessories) is substantially equivalent to the CADD-Solis system (pump and PC Tool) cleared under K170982[1] with respect to the indications for use, target populations, the basic infusion pump hardware and software used to control delivery of the infusion, technological characteristics, the delivery modes, and safety features.

[1] And K192860 for the administration sets