March 22, 2019

Halyard Health
% Neerav Parikh
Technical Leader, Regulatory Affairs
AVANOS
43 Discovery, Suite 100
Irvine, California 92618

Re: K181360
Trade/Device Name: ON-Q* Pump with Bolus
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MEB
Dated: February 22, 2019
Received: February 22, 2019

Dear Neerav Parikh:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 C. Dorgan -S

Digitally signed by Carolyn C. Dorgan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001800814, cn=Carolyn C. Dorgan -S
Date: 2019.03.22 14:09:14 -04'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K181360

Device Name
ON-Q* Pump with Bolus

Indications for Use *(Describe)*
ON-Q* Pump is intended to provide continuous delivery of medication (such as local anesthetics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and/or pain management. Routes of administration include: intraoperative site, peripheral nerve block, percutaneous and epidural.

ON-Q* Pump is indicated to significantly decrease pain and narcotic use when used to deliver local anesthetics to or around surgical wound sites, or close proximity to nerves, when compared to narcotic only pain management.

ON-Q* Pump with Bolus device is intended for users 18 years of age and older.

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.

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K181360 510(K) SUMMARY

Preparation Date:	March 22, 2019
Manufacturer's Name:	AVANOS Medical Inc. 43 Discovery, Suite 100, Irvine, CA 92618
Corresponding Officials:	Neerav Parikh Technical Leader, Regulatory Affairs
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	Nazanin Yacobi, PhD Associate Director, Regulatory Affairs
Telephone Number:	(949) 923-2323
E-mail Address:	Nazanin.Yacobi@avanos.com
Trade Name:	ON-Q* Pump with Bolus
Common or Usual Name:	Pump, Infusion, Elastomeric
Regulation Name:	Infusion Pump
Regulation Number:	21 CFR 880.5725
Product Code:	MEB
Device Class:	Class II
Primary Predicate Device:	K063530, ON-Q, PAINBUSTER, C-BLOC, SELECT-A-FLOW, ONDEMAND, HOMEPUMP, ECLIPSE, C-SERIES, ONE-STEP KVO, EASYPUMP

Device Description

The ON-Q* Pump with Bolus consists of an elastomeric pressure source (i.e. elastomeric pump) with an integrated administration set/line. The ON-Q* Pump with Bolus delivers continuous infusion (basal) and allows incremental fixed-volume boluses to be delivered on demand by the patient. In addition to the optional bolus component, the administration line may contain any of the following optional components:

- Filter
- Select-A-Flow variable flow rate assembly
- Y-adaptor

The bolus component controls the bolus and/or basal flow rate capability of the administration set that connects to the elastomeric pump. The bolus component is an integrated part of the pump system and cannot be used alone. The patient or healthcare provider presses a button to activate bolus delivery. The refill time determines the amount of time the patient must wait prior to receiving another full bolus dose.

Indications for Use

ON-Q* Pump is intended to provide continuous delivery of medication (such as local anesthetics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and/or pain management. Routes of administration include: intraoperative site, peripheral nerve block, percutaneous and epidural.

ON-Q* Pump is indicated to significantly decrease pain and narcotic use when used to deliver local anesthetics to or around surgical wound sites, or close proximity to nerves, when compared to narcotic only pain management.

ON-Q* Pump with Bolus device is intended for users 18 years of age and older.

The device is intended for prescription use only.

User Population

This device is used by pharmacists for pump filling only, by clinicians (Physicians, Nurses) for placement, infusion and adjustment of flow rate and by patients 18 years of age or older for adjustment of flow rate or activation of bolus.

Use Environment

The ON-Q* elastomeric pumps are suitable for use as an ambulatory device in hospitals, home environments or alternative care sites as directed by the healthcare professional.

Substantial Equivalence Discussion

Intended Use Comparison

The table below includes a comparison of the intended use between the new device and those of the predicate device:

Characteristic	**Predicate Device** K063530	**Subject Device** K181360
Indications for Use	The ON-Q* Pump is intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, percutaneous and epidural. The ON-Q* Pump is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic only pain management.	ON-Q* Pump is intended to provide continuous delivery of medication (such as local anesthetics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and/or pain management. Routes of administration include: intraoperative site, peripheral nerve block, percutaneous and epidural. ON-Q* Pump is indicated to significantly decrease pain and narcotic use when used to deliver local anesthetics to or around surgical wound sites, or close proximity to nerves, when compared to narcotic only pain management. ON-Q* Pump with Bolus device is intended for users 18 years of age and older.
Prescription Only or Over the Counter	Prescription Only	Prescription Only
Intended Population	This device is used by pharmacists for pump filling only, by clinicians (Physicians, Nurses)	This device is used by pharmacists for pump filling only, by clinicians (Physicians, Nurses)

Characteristic	**Predicate Device** K063530	**Subject Device** K181360
	for placement, infusion and adjustment of flow rate and by patients for adjustment of flow rate or activation of bolus.	for placement, infusion and adjustment of flow rate and by patients 18 years of age or older for adjustment of flow rate or activation of bolus.
Environment of Use	The ON-Q* elastomeric pumps are suitable for use as an ambulatory device in hospitals, home environments or alternative care sites as directed by the healthcare professional.	The ON-Q* elastomeric pumps are suitable for use as an ambulatory device in hospitals, home environments or alternative care sites as directed by the healthcare professional.

Discussions of differences in Indications for Use statement
Differences in the indications for use statement provide further clarification.

Discussions of differences in intended population
The difference in patient population was validated through summative human factors studies.

Discussions of differences in environment of use
The environment of use for the subject device is identical to the predicate device.

Technological Characteristics

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

Technological Characteristic	**Predicate Device** K063530	**Subject Device** K181360	**Comments**
Operating Principle Pump:	The elastomeric bladders function as the fluid reservoir and the pressure source. The pressure that pumps the fluid comes from the strain energy of the elastomeric properties of the bladder that is forced to expand when the pump is filled.	The elastomeric bladders function as the fluid reservoir and the pressure source. The pressure that pumps the fluid comes from the strain energy of the elastomeric properties of the bladder that is forced to expand when the pump is filled.	Same
Bolus:	Manual activation, depression of bolus delivery button, by the user is required to deliver the on-demand bolus of medication.	Manual activation, depression of bolus delivery button, by the user is required to deliver the on-demand bolus of medication.	Same
Control Mechanism Pump:	Mechanical force from an elastomeric bladder with a physical flow restrictor	Mechanical force from an elastomeric bladder with a physical flow restrictor	Same
Bolus:	Mechanical force from an internal spring with a physical flow restrictor	Mechanical force from an elastomeric bladder with a physical flow restrictor	See Comment #1
Energy Type	Elastomeric force (Mechanical)	Elastomeric force (Mechanical)	Same

Technological Characteristic	**Predicate Device** K063530	**Subject Device** K181360	Comments
Specifications			
Pump Fill Volume:	50 to 770 mL with fixed and variable flow rate configurations ranging from 0.5 to 250 mL/hour to 1 to 3 delivery sites	50 to 770 mL with fixed and variable flow rate configurations ranging from 0.5 to 250 mL/hour to 1 to 3 delivery sites	Same
Bolus Fill Volume:	5 mL bolus dose with 60 minute refill 5 mL bolus dose with 30 minute refill	3 mL bolus dose with 30 minute refill 3 mL bolus dose with 20 minute refill	See Comment #2
Material			
Pump	Acrylonitrile butadiene (ABS), silicone, Kraton, Latex, Ethylene Propylene, High Density Polyethylene (HDPE), Polyvinyl Chloride (PVC), Di(2-ethylhexhyl) phthalate (DEHP) Plasticizer	Acrylonitrile butadiene (ABS), silicone, Kraton, Latex, Ethylene Propylene, High Density Polyethylene (HDPE), Polyvinyl Chloride (PVC), Di(2-ethylhexhyl) phthalate (DEHP) Plasticizer	Same
Bolus	Silicone, PVC, polycarbonate	ABS, Silicone, stainless steel	See Comment #3
Biocompatibility	Biocompatible per ISO 10993	Biocompatible per ISO 10993	Same
Sterilization	Sterile per ISO-11135 via ethylene oxide (EO), single use EO Residuals per ISO 10993-7 Sterility Assurance Level (SAL) 10-6	Sterile per ISO-11135 via ethylene oxide (EO), single use EO Residuals per ISO 10993-7 Sterility Assurance Level (SAL) 10-6	Same Same Same
Packaging	Chevron-style Tyvek Pouch Conform to the requirements of ISO 11607	Chevron-style Tyvek Pouch Conform to the requirements of ISO 11607	Same Same
Shelf Life	2.5 years	2 years	See Comment #4

Discussions of differences in technological characteristics

Comment 1

The bolus controller of the subject device is driven by an elastomeric bladder instead of an internal spring like the predicate. However, bolus controller performance of the subject device was verified to ensure it reliably met performance requirements (See Comment #2). Therefore, the difference in control mechanism does not raise different questions of safety and effectiveness.

Comment 2

The bolus fill volume specifications are within the range of the predicate bolus fill volume. Since the types of medication delivered and routes of administration are unchanged, the change in specification does not raise different questions of safety and effectiveness.

Comment 3

The materials of construction of the bolus controller changed to ABS, Silicone, stainless steel. However, the contact category and duration of contact are unchanged between the subject and predicate device. In addition, biocompatibility

testing was provided to support the use of the new materials for the bolus controller. Therefore, the change does not raise different questions of safety and effectiveness.

Comment 4
The shelf life of the subject device was reduced from 2.5 years to 2 years compared to the predicate. Sterilization and device performance data was provided to support the 2 year shelf life and additional testing is ongoing to support expanded shelf life labeling. Therefore, the differences in shelf life does not raise different questions of safety and effectiveness.

Performance Testing

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

- Performance Verification
  - Bolus refill time/dispensed volume
  - Bolus flow rate
  - Bolus deployment force
  - Bolus lifecycle testing
  - Bolus pressure (leak) test
- Design Validation and Human Factors Evaluation
- Packaging Verification
- Sterilization Verification
- Biocompatibility, external communicating with indirect blood path contact for prolonged duration (>24 hours to ≤30 days
- Drug stability
- MR compatibility

A safety assurance case was provided for the ON-Q* Pump with Bolus, as recommended in the FDA guidance document, Infusion Pumps Total Product Life Cycle.

The following specific evidence was included within the assurance case to demonstrate that the subject device is verified/validated, risks adequately mitigated, and that the device is reliable for its intended use and to demonstrate substantial equivalence to the predicate device:

Device performance	• FDA Guidance “Infusion Pumps Total Product Life Cycle” • ISO 28620 Medical devices -- Non-electrically driven portable infusion devices • Verification of the bolus controller • Reliability of the bolus controller
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.
MR Safety	• ASTM F2503-13, “Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.”
Biocompatibility	• Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (Replaces #G87-1 #8294 Blue Book Memorandom) • ISO 10993 Biological evaluation of medical devices: Cytotoxicity, Sensitization, Irritation/Intracutaneous reactivity, Acute systemic toxicity, Sub-acute systemic toxicity, Genotoxicity, Pyrogenicity, and Hemolysis

Clinical Tests

Not Applicable

Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The ON-Q* Pump with Bolus is substantially equivalent to the predicate device cleared under K063530 with respect to the indications for use, target populations, treatment method, and technological characteristics.