DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 30, 2016

Halyard Health
Gwendolyn George
Technical Leader, Regulatory Affairs
5405 Windward Parkway
Alpharetta, Georgia 30004

Re: K161232
Trade/Device Name: ON-Q* EchoSpark Echogenic Catheter; ON-Q* T-bloc* Echogenic Continuous Nerve Block Kit
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO, CAZ
Dated: August 29, 2016
Received: August 30, 2016

Dear Gwendolyn George:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161232

Device Name
ON-Q* EchoSpark* Echogeneic Catheter

Indications for Use *(Describe)*
The ON-Q* EchoSpark* Echogenic Catheter is indicated for delivery of medication for regional anesthesia and pain management. Routes of administration may be perineural, intraoperative, or percutaneous.

The ON-Q* EchoSpark*Echogenic Catheter is indicated for patients undergoing continuous regional anesthesia and pain management procedures.

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:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161232

Device Name
ON-Q* T-bloc* Echogenic Continuous Nerve Block Kit

Indications for Use *(Describe)*
The ON-Q* T-bloc* Echogenic Continuous Nerve Block Kit is indicated for delivery of medication for regional anesthesia and pain management. Routes of administration may be perineural, intraoperative, or percutaneous.

The ON-Q* T-bloc* Echogenic Continuous Nerve Block Kit is indicated for patients undergoing continuous regional anesthesia and pain management procedures.

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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Section 5

510(k) Summary

ON-Q* Echogenic Catheter

Date Prepared: September 29, 2016

510(k) Submitter:

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TRADE NAME: ON-Q* EchoSpark Echogenic Catheter

CLASSIFICATION NAME: Anesthesia Conduction Catheter

DEVICE CLASSIFICATION: Class II

REGULATION NUMBER: 21 CFR 868.5120

PRODUCT CODE: BSO

PREDICATE DEVICE: ON-Q* Pain Relief System, QuikBloc* Over–the-Needle Catheter Set (K143164)

SUBJECT DEVICE DESCRIPTION: The ON-Q* Echogenic Catheter is a closed tip catheter composed of polyamide nylon (Pebax) tubing that contains two radiopaque barium sulfate stripes, black pad printed depth markings, and a stainless steel echogenic screw tip that is visible under ultrasound. The catheter assembly will also include a stylet composed of Nitinol wire with an ABS Finger holder and a polypropylene thread assist guide in a sterile Tyvek and polyester pouch.

INDICATIONS FOR USE: The ON-Q* EchoSpark Echogenic Catheter is indicated for delivery of medication for regional anesthesia and pain management. Routes of administration may be perineural, intraoperative, or percutaneous.

The ON-Q* EchoSpark* Echogenic Catheter is indicated for patients undergoing continuous regional anesthesia and pain management procedures.

CONTRAINDICATIONS: The ON-Q* Echogenic Catheter is not indicated for intravascular delivery.

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SUMMARY OF SUBSTANTIAL EQUIVALENCE: The technological characteristics, indications for use, and construction material of the ON-Q* Echogenic Catheter are substantially equivalent to the currently-marketed predicate device, ON-Q* Pain Relief System, QuikBloc* Over–the-Needle Catheter Set cleared under K143164. The same fundamental technology, assembly, labeling, packaging, and sterilization method, will be used. The distinguishing feature of the Echogenic Catheter is the stainless steel echogenic screw tip; which makes the catheter visible under ultrasound.

The ON-Q* Echogenic Catheter like the predicate device can be sold stand alone or in a kit.

The ON-Q* Echogenic Catheter Substantial Equivalence Table is provided below.

Characteristic	**Predicate Device QuikBloc* Over-the-Needle Catheter Set (K143164)**	**Subject Device ON-Q* Echogenic Catheter**
Regulation Product Code	BSO	**Same**
Manufacturer	Halyard Health	**Same**
Indications for Use	The ON-Q* QuikBloc* Over-the-Needle Catheter Set is indicated for delivery of medication (such as local anesthetics) for regional anesthesia and pain management. Route of administration may be intraoperative, percutaneous, or perineural. The ON-Q* QuikBloc* Over-the-Needle Catheter Set is contraindicated for the epidural space.	The ON-Q* EchoSpark Echogenic Catheter is indicated for delivery of medication for regional anesthesia and pain management. Routes of administration may be perineural, intraoperative, or percutaneous. The ON-Q* EchoSpark* Echogenic Catheter is indicated for patients undergoing continuous regional anesthesia and pain management procedures.
Sterilization Method	Ethylene Oxide	**Same**
Catheter Tubing composition	Pebax	**Same**
Echogenic screw tip	N/A	Stainless Steel
Echogenic	N/A	Yes
Depth Markings	Graduated depth markings every 10 mm	**Same**
Radiopaque Stripes	Barium sulfate stripes	**Same**
Labeling	Case and sterile pack with identification label of catheter type, size etc. and IFU	**Same**
MRI Compatibility	MR Safe	MR UnSafe
Single Use Device	Yes	**Same**
Packaging	Chevron Style Sterile Tyvek Pouch ASTM F1980-07 ASTM D4169-09 ASTM F 2096-11 ASTM F 1886-09 ISO 15223:2012 ISO 11607-1:2006	**Same**

Characteristic	Predicate Device QuikBloc* Over-the-Needle Catheter Set (K143164)	Subject Device ON-Q* Echogenic Catheter
Performance Testing Data	ISO:10555-1:2013 ASTM F 1980-07 EN-13868:2002 ISO:10555-5:2013	All applicable performance standards are the same. ISO 10555-5:2013 does not apply because this is not an over the needle catheter.
Biocompatibility	ISO:10993-1:2009 Compliant ISO:10993-3:2003 No statistically significant increase in the number of revertant colonies compared to negative control ISO:10993-4:2002 No statistically significant difference compared to negative control ISO:10993-5:2009 Acceptance Criteria ≤ Grade 2 ISO:10993-6:2007 No significant difference compared to the controls. ISO:10993-10:2010 Acceptance Criteria: Sensitization Index <3 Acceptance Criteria: Test article mean score- control article mean score ≤1 ISO:10993-11:2012 None of the test animals show greater biological reaction than control animals.	**Same**
Sterilization	ISO 10993-7:2008 ISO 11135-1:2007	**Same**

The Indications for Use statements of the subject and predicate devices are the same (i.e., both are intended for regional anesthesia and pain management) except for the order in which the routes of administration are listed, additional specificity regarding indicated patient population, and the predicate includes a contraindication for use of the device in the epidural space. The subject device does not contain a needle; therefore, the predicate contraindication is not applicable to this device. The listed order of routes of administration, additional specificity regarding indicated patient population, and removal of the non-applicable contraindication are not critical to the intended therapeutic or surgical use of the device and do not affect the safety and efficacy of the device when used as labeled.

CONCLUSION: Based on the design, labeling, and results of testing, the proposed new Echogenic Catheter does not raise any different questions of safety or effectiveness. The device is as safe, as effective and performs as well as or better than the predicate. The Echogenic Catheter is substantially equivalent to the predicate ON-Q* QuikBloc* Over-the-Needle Catheter Set.

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Section 5

510(k) Summary

ON-Q* T-bloc*Echogenic Continuous Nerve Block Kit

Date Prepared: September 29, 2016

510(k) Submitter:
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TRADE NAME: ON-Q* T-bloc* Echogenic Continuous Nerve Block Kit

CLASSIFICATION NAME:

DEVICE CLASSIFICATION: Class II

REGULATION NUMBER:

PRODUCT CODE: CAZ

PREDICATE DEVICE: Peripheral Nerve Block Tray (K073187)

SUBJECT DEVICE DESCRIPTION: ON-Q* T-bloc* Echogenic Continuous Nerve Block Kit is designed for the Regional Anesthesia market to deliver medication for regional anesthesia and pain management. The Kit contains multiple components; one being Halyard Health's new Echogenic Catheter. The Echogenic Catheter is a closed tip catheter composed of polyamide nylon (Pebax) tubing that contains two radiopaque barium sulfate stripes, black pad printed depth markings, and a stainless steel echogenic screw tip that is visible under ultrasound. The catheter assembly will also include a stylet composed of Nitinol wire with an ABS Finger holder and a polypropylene thread assist guide in a sterile catheter sleeve composed of Tyvek and polyester.

INDICATIONS FOR USE: The ON-Q* T-bloc* Echogenic Continuous Nerve Block Kit is indicated for delivery of medication for regional anesthesia and pain management. Routes of administration may be perineural, intraoperative, or percutaneous.

The ON-Q* T-bloc* Echogenic Continuous Nerve Block Kit is indicated for patients undergoing continuous regional anesthesia and pain management procedures.

CONTRAINDICATIONS: The ON-Q* T-bloc* Echogenic Continuous Nerve Block Kit is not indicated for intravascular delivery.

SUMMARY OF TECHNOLOGIES: The technological characteristics, instructions for use, construction, and components of the ON-Q* T-bloc* Echogenic Continuous Nerve Block Kit are substantially equivalent to the currently marketed predicate device, Peripheral Nerve Block Tray cleared under K073187. The same sterilization method, fundamental technology, packaging, assembly and labeling will be used. The distinguishing feature of the ON-Q* T-bloc* Echogenic Continuous Nerve Block Kit is the Echogenic Catheter which will replace the existing Epimed Spirol® Catheter found in the predicate tray. The differences between the subject and predicate devices do not raise different questions of safety and effectiveness. Table 5.1 Tray comparison, outlines the differences in the predicate and subject devices.

TABLE 5.1 Kit Comparison

Characteristic	Predicate Device Peripheral Nerve Block Tray (K073187)	Subject Device ON-Q* T-bloc* Echogenic Continuous Nerve Block Kit
Regulation Product Code	CAZ	CAZ
Indications for use	The Peripheral Nerve Block Tray is used for administration of regional or local anesthesia to a patient.	The ON-Q* T-bloc* Echogenic Continuous Nerve Block Kit is indicated for delivery of medication for regional anesthesia and pain management. Routes of administration may be perineural, intraoperative, or percutaneous. The ON-Q* T-bloc* Echogenic Continuous Nerve Block Kit is indicated for patients undergoing continuous regional anesthesia and pain management procedures.
Sterilization Method	Ethylene Oxide	**SAME**
Single Use Device	Yes	**SAME**
Packaging	Sterile Tyvek Pouch Sterile .035" HDPE tray with Tyvek Lid	**SAME**
Catheter Component	20 GA x 24 in (61 cm) Spirol® Catheter, with Inner Stylet and Thread Assist Guide	20 GA x 24 in (61 cm) Echogenic Catheter, with Inner Stylet and Thread Assist Guide
Stylet	Stainless Steel	Nitinol

The Indications for Use statements of the subject and predicate devices have the same intended use (i.e., both are intended for regional anesthesia and pain management); however, the subject device indications for use has been expanded to identify the routes of administration and inclusion of the indicated patient population. The identification of the routes of administration and inclusion of the indicated patient population are not critical to the intended therapeutic or surgical use of the device and do not affect the safety and efficacy of the device when used as labeled.

Conclusion: The ON-Q* T-bloc* Echogenic Continuous Nerve Block Sets & Tray have substantially equivalent Indications for use, sterilization methods, packaging, and kit components as the predicate device, Peripheral Nerve Block Tray (K073187). The design enhancements of the subject device catheter raises no different questions of safety and effectiveness. The device is as safe, as effective, and performs as well as or better than the predicate.