DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 2,2014

Kimberly-Clark Corporation
Ms. Maria E. Wagner
Senior Regulatory Affairs Specialist
43 Discovery, Suite 100
Irvine, CA 92618

Re: K143164
Trade/Device Name: On-Q QuikBloc Over-the-Needle (OTN) Catheter Set
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: October 21, 2014
Received: November 3, 2014

Dear Ms. Wagner:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Erin I. Keith, M.S.
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)* K143164

Device Name: ON-Q* QuikBloc* Over-the-Needle Catheter Set

Indications for Use *(Describe)*

The ON-Q* QuikBloc* Over-the Needle Catheter Set is indicated for delivery of medication 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date of Summary Prepared:	November 25, 2014
Applicant:	Halyard - Irvine 43 Discovery, Suite 100 Irvine, CA 92618
Official Correspondent:	Maria E. Wagner Sr. Specialist, Regulatory Affairs Tel: 949.923-2324 Fax: 949.923-2401 email: maria.wagner@hyh.com
Trade Name:	ON-Q* QuikBloc* Over-the-Needle (OTN) Catheter Set
Classification Name:	Anesthesia Conduction Catheter
Device Classification and Product Code:	Class II per 21 CFR §868.5120 Product Code - BSO
Existing/Predicate Devices:	Halyard Health currently markets the I-Flow Catheter and consists of three design options which can utilize infusion segments ranging from epidural to 10 inches K043456). The EchoBright* Echogenic PNB Needle is a peripheral nerve block insulated needle with graduated centimeter markings to determine the depth of the needle advancement into tissue. The needle incorporates a series of patterns designed to optimally scatter the deflection of ultrasound waves for the needle such that a high percentage reach the ultrasound probe for improved visualization of the needle position in tissue (K111355).
Device	The ON-Q* QuikBloc* Over-the-Needle (OTN) Catheter Set, subject

Description:	of this special submission is substantially equivalent to the I-Flow Catheter cleared in K043456 and Needle K111355. ON-Q* QuikBloc* Over-the-Needle (OTN) Catheter Sets are available in four product codes (20 GA x 4" Needle, 16 GA x 3" Catheter (with and without Stimulating needle); 20 GA x 6" Needle, 16 GA x 5" Catheter (with and without stimulating needle)). The kits include: 1) ON-Q* QuikBloc* Over-the-Needle Catheter Set (some models include an integrated stimulating cable) 2) Removable Needle Wing 3) Non-DEHP 24 inch Needle Extension Set, 4) Non-DEHP 6 inch Catheter Extension Set 5) Connector Securement Device 6) Occlusive Dressing 7) Adhesive Strips 8) Catheter ID label These devices are sold as disposable, sterile, single use, devices.
Target Market:	Regional analgesia and anesthesia
Primary Application:	Peripheral Nerve Block procedures.
Intended Use:	ON-Q* Pain Relief System QuikBloc* Over-the-Needle Catheter Set is indicated for delivery of medication for regional anesthesia and pain management. Route of administration may be intraoperative, percutaneous or perineural.
Technological Characteristics:	Both the modified ON-Q* Pain Relief System QuikBloc* Over-the-Needle Catheter Set and the predicate I-Flow Catheter (K043456) have the same basic fundamental technological characteristics. Both catheters deliver medication. Routes of administration may be intraoperative, percutaneous, or perineural. The only difference in the ON-Q* Pain Relief System QuikBloc* Over-the-Needle Catheter Set is that it is open ended to fit a needle through the catheter.
Performance Data:	Components used in the ON-Q* Pain Relief System QuikBloc* Over-the-Needle Catheter Sets have been evaluated for biocompatibility by their corresponding vendors. Gamma or EO sterilized samples of the components as mentioned below were tested *in vitro* or in laboratory animals for the listed toxicological end-points in accordance with the respective sections in ISO 10993 guidelines and Good Laboratory Practices. The results from these studies revealed no adverse reaction to the test articles and no adverse effects. In addition, these components have 510(k) clearance in the US, which indicate that they have been cleared and have been deemed safe for their intended use. Results of design verification and validation testing demonstrated

that the ON-Q* QuikBloc* Over-the-Needle Catheter Set functions as designed and can be operated by the user as intended through the user interface and instructions provided.

Conclusion: The ON-Q* Pain Relief System QuikBloc* Over-the-Needle Catheter Set is as safe and effective and performs as well as the predicate devices.