



January 25, 2018

Smiths Medical ASD, Inc.
Michael Johnson
Sr. Regulatory Affairs Specialist
6000 Nathan Lane North
Minneapolis, Minnesota 55442

Re: K171968

Trade/Device Name: EchoGlo Peripheral Nerve Block Needle: Single Shot and EchoGlo Peripheral Nerve Block Needle: Continuous Catheter
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: December 20, 2017
Received: December 22, 2017

Dear Michael Johnson:

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.

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.

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,

Tara A.
Ryan -S

Digitally signed by Tara A. Ryan -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Tara A. Ryan -S,
0.9.2342.19200300.100.1.1=1300030749
Date: 2018.01.25 08:49:18 -05'00'

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

Indications for Use

510(k) Number (*if known*)

K171968

Device Name

EchoGlo™ Peripheral Nerve Block Needle: Single Shot

EchoGlo™ Peripheral Nerve Block Needle: Continuous

Indications for Use (*Describe*)

The EchoGlo™ Peripheral Nerve Block Needle: Single Shot

This device is intended for use in the administration of regional anesthetic blocks.

The EchoGlo™ Peripheral Nerve Block Needle: Continuous

This device is intended for use in the administration of regional anesthetic blocks.

Intended population is adults.

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
PRASStaff@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."

1. ADMINISTRATIVE INFORMATION

510(k)	K171968
Applicant's Name and Address	Smiths Medical ASD, Inc. 6000 Nathan Lane North Minneapolis, MN 55442 USA
Contact Person	Michael R. Johnson Sr. Regulatory Affairs Specialist Phone: 763-383-3341 Fax: 763-383-3679 Email: mike.johnson@smiths-medical.com
Date	December 14, 2017
Regulation No.	21 CFR § 868.5150
Regulation Name	Anesthesia conduction needle
Primary Product Code	BSP
Trade Name	EchoGlo™ Peripheral Nerve Block Needle: Single Shot EchoGlo™ Peripheral Nerve Block Needle: Continuous

2. DEVICE INFORMATION

	Predicate Device	Subject Device
Trade Name	SONO Tap Tuohy Sono	EchoGlo™ Peripheral Nerve Block Needle: Single Shot EchoGlo™ Peripheral Nerve Block Needle: Continuous
Regulation No.	21 CFR § 868.5150	21 CFR § 868.5150
Regulation Name	Anesthesia conduction needle	Anesthesia conduction needle
Regulatory Class	II	II
Product Code	BSP	BSP
510(k)	K113207	K171968

3. DEVICE DESCRIPTION

The EchoGlo™ Peripheral Nerve Block (PNB) Needle consist of a polycarbonate luer hub, stainless steel cannula and a polyethylene sheath. The needle cannula will be supplied with a bevel tip or a Tuohy tip. The EchoGlo™ PNB Needle will be used for peripheral nerve block under ultrasound guidance. The distal end of the cannula has been engraved with two bands to increase ultrasound visibility by optimally reflecting ultrasound waves. These needles are provided as sterile, non-pyrogenic, single-use disposable devices. The needles may be used for single shot peripheral nerve block or for continuous infusion nerve block. The EchoGlo™ PNB Needle used for a single shot procedure will be supplied in a pouch along with a 24 inch extension set. The extension set will consist of polyvinyl chloride (PVC) tubing and have a Female luer at one end of the tubing and a Male luer at the opposite end of the tubing.

4. INDICATIONS FOR USE

The EchoGlo™ Peripheral Nerve Block Needle: Single Shot

This device is intended for use in the administration of regional anesthetic blocks.

The EchoGlo™ Peripheral Nerve Block Needle: Continuous

This device is intended for use in the administration of regional anesthetic blocks.

Intended population is adults.

5. SUBSTANTIAL EQUIVALENCE DISCUSSION

Indications for Use

The Echoglo indications for use is similar to the predicate device. Both devices include enhanced for ultrasound visibility, similar transient delivery and the option to facilitate placement of a catheter.

A. Both the subject and predicate devices are enhanced for ultrasound visibility. The EchoGlo™ needles are enhanced for ultrasound visibility via grooved echogenic feature. The EchoGlo™ needles also have visible bands which identify the needle length and needle insertion depth in 1cm increments after echogenic feature, visible to the eye without ultrasound imaging.

B. Both the subject and predicate devices offer similar transient use.

C. Both the subject and predicate devices offer the option to facilitate placement of a catheter. Testing demonstrating equivalency for placement.

Summary of Technology Characteristics

The Smiths Medical EchoGlo Peripheral Nerve Block Needles and predicate devices are both designed for enhanced ultrasound visibility, delivery of regional anesthesia, and to facilitate placement of a catheter. The Smiths Medical EchoGlo™ Peripheral Nerve Block Needles has similar technological characteristics as the predicate device. Both subject and predicate device incorporate 1cm incremented visible depth markings to monitor insertion depth through ultrasound imaging. The subject device and predicate devices are prescribe by physician only, for single use and provided Ethylene Oxide (EO) sterile to the healthcare facility and/or end user.

The difference between the predicate is the Smiths EchoGlo has echogenic visible bands with helical markers while the SonoTAP and Tuohy Sono include diamond shape markers. Additionally, the Echoglo offers a Bevel tip in 20G-22G, and a Tuohy tip in 18G.

A comparative analysis of the technological characteristics is provided in Table 5-1.

Table 5-1

Characteristic	Predicate Device K113207	Subject Device K171968	Discussion
Company	Pajunk GMBH	Smiths Medical	NA
FDA Product Code & CFE	BSP 21 CFR 868.5150.	BSP 21 CFR 868.5150.	Same
Trade Name	SONO Tap Tuohy Sono	EchoGlo™ Peripheral Nerve Block Needle:	NA

Characteristic	Predicate Device K113207	Subject Device K171968	Discussion
		Single Shot EchoGlo™ Peripheral Nerve Block Needle: Continuous	
Product	Needle, Conduction, Anesthetic (w/wo introducer)	Single Shot and Continuous Nerve Block Needle	NA
Common / Classification Name	Anesthesia conduction needle	Anesthesia conduction needle	Same
Indications for Use	The cannulas/ needles for anesthesia and analgesia enhanced for ultrasound visibility - Tuohy Sono, Sono TAP, Quincke Sono, Chiba Sono, Sono and Crawford Sono – are intended for the transient delivery of anesthetics to provide regional anesthesia and analgesia or to facilitate placement of a catheter	The EchoGlo™ Peripheral Nerve Block Needle: Single Shot This device is intended for use in the administration of regional anesthetic blocks. The EchoGlo™ Peripheral Nerve Block Needle: Continuous This device is intended for use in the administration of regional anesthetic blocks.	Similar. Both are enhanced for ultrasound visibility. Also, both are intended for the delivery of regional anesthesia, or to facilitate placement of a catheter.
Hospital Location Use	ICU/OR	ICU/OR	Same
Visibility feature	Etched cannula/needle to enhance ultrasound visibility. The needle cannula is equipped with a specific diamond shaped reflector pattern that is designed to reflect ultrasound waves.	Etched cannula/needle to enhance ultrasound visibility. A special helical-shaped groove design is cut into the needle cannula. The grooves are designed to optimally reflect ultrasound waves to make the needle more visible under ultrasound.	Similar. Both are etched needles that are designed to enhance visibility under ultrasound. Difference is the etched pattern.
Proximal End Connection	Luer, Per ISO 594-1, and ISO 594-2	Luer, Per ISO 594-1, and ISO 594-2	Same
Single Use	Yes	Yes	Same
Sterilization Method	EtO	EtO	Same
Tip Design	Tuohy, Bevel	Tuohy, Bevel	Same
Needle Gauge	Tuohy SONO : 16G – 26G	Bevel : 20G-22G Tuohy: 18G	Similar. Subject diameter is

Characteristic	Predicate Device K113207	Subject Device K171968	Discussion
	Quincke SONO: 16G - 26G Sono TAP, Chiba SONO: 16G - 26G Crawford SONO: 16G - 26G		between predicate's gauge range
Needle Length	Tuohy SONO: 20mm-180mm Sono TAP, Quincke SONO: 20mm-180mm Chiba SONO: 20mm-180mm Crawford SONO: 20mm-180mm	Single Shot: 35-150mm Continuous: 50-150mm	Similar. Subject length is within predicate's length range
Cannula Material	Stainless steel	Stainless steel	Same
Needle Hub Material	Polycarbonate	Polycarbonate	Same
Sheath Material	Polyethylene	Polyethylene	Same
Extension Set Tubing Material	Polyvinyl chloride (PVC)	Polyvinyl chloride (PVC)	Same
Extension Set Male Luer Material	Polyacrylic	PVC	Similar
Extension Set Female Luer Material	PVC	PVC	Same

6. SUMMARY OF NON-CLINICAL TESTING

The Smiths Medical EchoGlo™ Peripheral Nerve Block Needle was evaluated via non-clinical performance testing to demonstrate the devices are substantially equivalent the predicate devices. All testing met pre-established specifications, and successfully demonstrated that the EchoGlo™ Peripheral Nerve Block Needle performed as intended. A summary of the Non-Clinical performance testing is in Table 5-2. Biological and Bench testing was conducted to the Standards in Table 5-3.

Table 5-2 – Non-Clinical Performance Testing

Category	Evaluation	Standards
Biocompatibility	Cytotoxicity	ISO 10993-7:2009: Biological evaluation of medical devices— Part 5: Tests for in vitro cytotoxicity
	Sensitization	ISO 10993-10:2010: Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization
	Acute systemic toxicity	ISO 10993-11:2006: Biological evaluation of medical devices— Part 11: Tests for systemic toxicity
	Material-Mediated Pyrogenicity	USP<151>Pyrogen Test
	Particulate Matter in Injections	USP<788>:2012 Particulate Matter in Injections
	Exaggerated Leachables	ISO 10993-17:2002: Biological evaluation of medical devices— Part 17: Establishment of allowable limits for leachable substances
	Hemocompatibility	ISO 10993-4:2002/(R)2013 & A1:2006/(R)2013: Biological evaluation of medical devices - Part 4: Selection of tests for interaction with blood
Packaging	Existing packaging material for currently marketed devices will be used for the packaging of the EchoGlo™ Peripheral Nerve Block Needle. Packaging integrity test were performed to ensure packaging meet specifications. For details reference Section 14.3	ASTM D4169:2016: Standard practice for performance testing of shipping containers and systems. ASTM F1886:2013: Determining integrity of seals for flexible packaging by visual inspection. ASTM F2825:2015: Standard practice of climatic stressing of packaging systems for single parcel delivery. ASTM F88/F88M:2015: Standard

Category	Evaluation	Standards
		test method for seal strength of flexible barrier materials. ASTM F2096:2011: Standard test method for detecting gross leaks in medical packaging by internal pressurization. ISO 11607-1:2006/(R):2010: Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems, and packaging systems.
Device Performance	Gauging (T=0, T=6 months accelerated aging (AA)) Leakage, Air (T=0, T=6 months AA) Leakage, Liquid (T=0, T=6 months AA) Ease of Assembly (T=0, T=6 months AA) Separation Force (T=0, T=6 months AA) Resistance to Overriding (T=0, T=6 months AA) Unscrewing Torque (T=0, T=6 months AA) Stress Cracking (T=0, T=6 months AA)	ISO 594-1: Conical fittings with a 6% (luer) taper for syringes, needles, and certain other medical equipment – Part 1: General Requirements ISO 594-2 second ed. 1998-09-01: Conical Fittings with a 6% taper (luer) for syringes, needles, and certain other medical equipment - Part 2: Lock fittings
	Needle Inspections Bond – Needle and hub (T=0, T=6 months AA) Limits of Acidity/Alkalinity Patency of Lumen Limits for Extractable materials	ISO 7864 Fourth Edition: 2016-08-01: Sterile hypodermic needles for single use – Requirements and test methods
	Needle Inspections Needle Stiffness Resistance to Breakage Resistance to Corrosion	ISO 9626 Second Edition 2016-08-01: Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
	Bond Pull – Extension set (T=0, T=6 months AA) Demonstration Penetration Force Ultrasound Visibility	N/A
Human Factors	Evaluate user interface	FDA guidance, <i>Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff</i> (3 February 2016)

Table 5-3 - Biological and Bench Testing

Recognition Number	Standard Number	Assessment
14-452	ISO 11135 2 nd Edition 2014	Sterilization Of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine

Recognition Number	Standard Number	Assessment
		Control Of A Sterilization Process For Medical Devices. (Sterility)
2-156	ISO 10993-1:2009 R 2013	Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process
6-11	ISO 594-1	Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment – Part 1: General Requirements
6-129	ISO 594-2 Second Ed. 1998-09-01	Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment - Part 2: Lock Fittings
14-457	11607-1:2006/(R)2010	Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems [Including: Amendment 1 (2014)]
2-234	ISO 10993-4:2002/(R)2013 & A1:2006/(R)2013	Biological evaluation of medical devices - Part 4: Selection of tests for interaction with blood
14-278	10993-7:2008(R)2012	Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
2-118	AAMI ANSI ISO 10993-11:2006/(R)2010	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
14-227	AAMI ANSI ISO 11737-1:2006 (R)2011	Sterilization Of Health Care Products - Microbiological Methods - Part 1: Determination Of The Population Of Microorganisms On Product
14-360	ANSI/AAMI ST72:2011	Bacterial Endotoxins - Test Methods, Routine Monitoring, And Alternatives To Batch Testing
6-379	ISO 7864 Fourth Edition 2016-08-01	Sterile Hypodermic Needles For Single Use - Requirements And Test Methods
6-380	ISO 9626 Second Edition 2016-08-01	Stainless Steel Needle Tubing For The Manufacture Of Medical Devices - Requirements And Test Methods
5-108	ASTMD 4169-16 2014	Standard Practice for Performance Testing of Shipping Containers and Systems
N/A	USP<151>	Pyrogen Test
N/A	USP<788>:2012	Particulate Matter in Injections

7. SUBSTANTIAL EQUIVALENCE CONCLUSION

The Smiths Medical EchoGlo™ Peripheral Nerve Block Needle is substantially equivalent to the

predicate device based on comparisons of the device classifications, intended use, and technological characteristics. Verification and validation tests confirmed the suitability of the subject devices for its intended uses. The results of biocompatibility testing and performance confirmed the substantial equivalence of the EchoGlo™ Peripheral Nerve Block Needle. The test results do not raise different safety or performance questions, and confirmed that the EchoGlo™ Peripheral Nerve Block Needle is substantially equivalent to the predicate devices.