DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 6, 2017

PAJUNK® GmbH Medizintechnologie
Christian Quass
Director Regulatory Affairs
Karl-Hall-Str. 1
78187 Geisingen
Baden-Wuerttemberg
GERMANY

Re: K162086
Trade/Device Name: MultiStim ECO
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: Class II
Product Code: BXN
Dated: December 8, 2016
Received: December 9, 2016

Dear Christian Quass:

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
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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)*

Device Name
MultiStim ECO

Indications for Use *(Describe)*
Pajunk's MultiStim ECO is intended for nerve stimulation during anaesthesia delivery; first for identification of peripheral nerves and second for localizations. This device is indicated for adults only.

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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510(k) Summary as required by 21 CFR 807.92(c).

Date of Preparation: January 6th 2017

Document Control Number: _____

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Device Information:

Device Name:	MultiStim ECO
Document Control Number	
Classification Name:	**Battery Powered Nerve Stimulator**
Classification Reference:	21 CFR § 868.2775
Product Code:	BXN
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	Anesthesiology

Predicate Device Information:

Device Name:	MultiStim SENSOR
Document Control Number	K061172
510(k) title	PAJUNK MULTISTIM SENSOR NERVE STIMULATORS
510(k) owner	Pajunk GmbH Medizintechnologie Karl-Hall-Str. 1 78187 Geisingen, Baden-Wuerttemberg, Germany
Classification Name:	Peripheral Nerve Stimulator
Classification Reference:	21 CFR § 868.2775
Product Code:	BXN, KOI
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	Anesthesiology

Device Description

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PAJUNK® GmbH Medizintechnologie is submitting this *510(k)* for the MultiStim ECO *handheld*, *battery powered* peripheral nerve stimulator.

The use of nerve stimulators for the identification of peripheral nerves is established as a routine procedure.

In this way simultaneous control of the distance of the cannula to the nerve using stimulation enables an optimization of the puncture accuracy for each anaesthetist.

The MultiStim ECO is a nerve stimulator that is suitable for stimulation technique. It is characterized in particular by the following properties:

- small, compact device – complies with the requirements of combined procedures
- Simple operation – manual settings are limited to the parameters proven in practice
- No additional patient cable – cannula is directly connected to the device

The MultiStim ECO settings are adapted to standard applications as well as the intuitively operated keyboard enable one-hand operation. A keystroke is all that is necessary for activation after switching on – an additional function selection is not required.

Basic functions/ features:

Fixed defined settings:

The frequency is predefined at 1 Hz and the stimulation pulse width at 0.1 ms.

Due to safety reasons, stimulation is first activated or deactivated by a touch of the stimulation button.

Variation of the current strength

Depending on the special requirements of an application, the current strength can be gradually set on a six-level amplitude scale from 0.2 to 2.0 mA. Arrow buttons are used for the plus/minus key.

Fixation by an adhesive electrode

The MultiStim ECO has a pushbutton connection on the lower side of the device and is clicked directly on the adhesive electrode. The stimulateable cannula is connected directly to the MultiStim ECO.

Sequence of use:

The needle (e.g. SonoPlex, UniPlex, separately available and cleared for market) is directly connected to the MultiStim ECO via the stimulation cable equipped with a Ø2mm plug.

The stimulator is turned on. The needle then is advanced through the patient´s skin and directed towards the nerve (e. g. via landmark technique or by means of ultrasound). The stimulation is activated to verify the position of the needle´s tip.

Once the desired target is reached, the stimulator is turned off and the anesthetic agent is applied.

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Intended Use

Subject device:

Pajunk's MultiStim ECO is intended for nerve stimulation during anaesthesia delivery; first for identification of peripheral nerves and second for localizations. This device is indicated for adults only.

Predicate Device K061172:

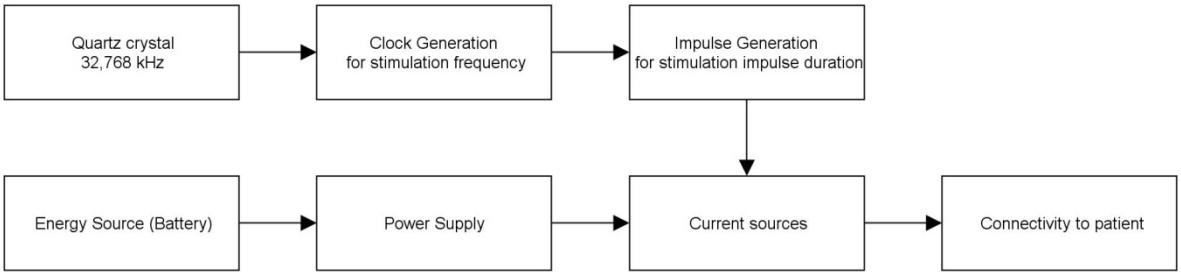
Pajunk's MultiStim SENSOR is intended for nerve stimulation during anaesthesia delivery; first for percutaneous identification of peripheral nerves and second for percutaneous localizations. This device is indicated for adults only.

Determination methods and results of Substantial Equivalence Determination:

The intended use as well as the basic technical description of the stimulator which is relevant to clinical use is identical to the predicate device K061172 and has been cleared in 510(k) sent in earlier by the sponsor and cleared by the Food and Drug Administration.

The pulse is generated by pre-built hardware settings only. The options for the user are realized using a hardware solution.

Both devices generate the individual pulse with a quartz crystal:



The difference between the predicate device, the MultiStim SENSOR and the subject device, the MultiStim ECO is the ECO does neither contain nor employ any software.

The clinical technique and the indications for use are absolutely identical. None of these is affected by the hardware solution as it is subject to this submission.

Intended Use

Intended Use Subject Device

Pajunk's MultiStim ECO is intended for nerve stimulation during anaesthesia delivery; first for identification of peripheral nerves and second for localizations. This device is indicated for adults only.

Intended Use K061172 (Predicate Device)

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Pajunk's MultiStim SENSOR is intended for nerve stimulation during anaesthesia delivery; first for percutaneous identification of peripheral nerves and second for percutaneous localizations. This device is indicated for adults only.

Discussion of differences

For both, the subject device and the predicate device the indications for use is exactly the same. The Predicate device as well as the subject device is used with stimulation needles. The word “percutaneous” has been eliminated in the subject submission because it is obsolete and even misleading.

Conclusion: Substantially Equivalent

Side-by-side comparison table

Characteristics	**Predicate device** **MultiStim SENSOR**	**Subject Device** **MultiStim ECO**	***Result of comparison, if necessary with rationale***
Picture (not for scale)			n.a.
Dimensions	65mm x 120mm x 27mm	65mm x 93mm x 20mm	n.a.
FDA Classification	Class II	Class II	Identical
FDA Product Code	BXN	BXN	Identical
FDA Common Name	Peripheral Nerve Stimulator	Peripheral Nerve Stimulator	Identical
FDA Classification name	868.2775	868.2775	Identical
Biocompatibility	ISO 10993-1 compliant material		Identical
Labeling	21 CFR and European Medical Devices Directive compliant		Identical
Packaging	Hard Case	Hard Case	Similar
Overall design			
Physical configuration	Handheld	Handheld	Identical
User Input	Menu structure in display, pushbutton, membrane switch	Membrane switch, direct feedback	Reduced
User Feedback	LED, Display	LED	Reduced

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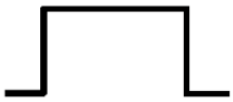
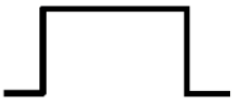
Characteristics	**Predicate device** **MultiStim SENSOR**	**Subject Device** **MultiStim ECO**	***Result of comparison, if necessary with rationale***
Power Supply	Battery	Battery	Identical
Accessories	Commonly available self-adhesive electrode Patient Main Cable Needle Patient Main Cable Handle Stimulation Handles (monopolar, bipolar) Extension cable	Commonly available self-adhesive electrode Extension Cable	S. E.
Compatible Devices	Anaesthesia Conducting Needles: SonoPlex-series UniPlex-series Monopolar Handle Bipolar Handle	Anaesthesia Conducting Needles: SonoPlex-series UniPlex-series	S. E.
Technological impulse generation	Software-controlled	Hardware-Controlled	Different Subject is intended to be easy to handle
Cleaning/ Desinfaction	Disinfect/ clean prior to each use: Only use soft, moistened cloths to clean and disinfect the device and the electrode cables. Water, soapsuds or denaturated alcohol are particularly suitable for this purpose. Take care that no water or moisture enters into the device. Alcohol, or commercially available alcohol based disinfectants containing no methyl alcohol may be used for disinfection. Attention: The following agents may not be employed for cleaning purposes: trichloroethylene, acetone, butanone (methyl ethyl ketone), benzene, methyl alcohol or cellulose thinner (cellosolve, etc.).		Identical
Features/ Technology			
Pulse form	Square pulse 	Square pulse 	Identical
Stimulation pulse width	0.1 ms	0.1 ms	Identical
Impulse current	0,0mA – 6,0mA (needle) 0,0mA – 60mA (PEG handle)	0,20 mA/ 0,50 mA/0,70 mA/ 1,00 mA/ 1,50 mA/ 2,00 mA	S. E.
Maximal Voltage	$90V_{SS}$	max. 24 V	Different; Higher values in predicate due to percutaneous indication
Type of device	BF	BF	identical

Characteristics	**Predicate device** **MultiStim SENSOR**	**Subject Device** **MultiStim ECO**	***Result of comparison, if necessary with rationale***
Battery	9 V alkali-manganese batteries (VARTA 4022, DURACELL MN 1604)	2x 1.5-volt N batteries (LR1, LADY, size N)	Different
Resistance	0 kOhm -60 kOhm	0 kOhm -12 kOhm	Different; Greater bandwidth in predicate due to percutaneous indication
Stimulation Frequency	1 Hz/2 Hz	1 Hz	Equivalent 1 Hz is most commonly used
Stimulation impulse bandwidth:	0,05 ms / 0,10 ms / 0,20 ms/ 0,30 ms/0,50 ms/1,00 ms	0,10 ms	Different Subject device for needles only
Operating Conditions	Temperature: 10°C to 30°C Atmospheric humidity: 20% – 65%	Temperature: 10 °C to 30 °C Air humidity: 20 % – 65 % Air pressure: 700 hPa to 1060 hPa	Identical
Transportation and Storage	Temperature: 10°C to 30°C Atmospheric humidity: 20% to 65%	Temperature: 10 °C to 30 °C Air humidity: 20 % – 65 % Air pressure: 700 hPa to 1060 hPa	Identical
Protection Type IEC 60529	IP54	IP54	Identical
Sound level	Adjustable Sound level selection: off, low, medium, loud, very loud	Adjustable Sound level selection: medium, loud, soft	Different Subject device is less complex
Functional Self Test	Self-Check Short-Circuit test	Self-Check Short-Circuit test	Identical
Battery Warning	optical	optical	Identical

Performance Testing:

Both devices, the MultiStim ECO and the MultiStim SENSOR generate a rectangular 1Hz impulse. This impulse is generated by a quartz crystal.

The output signals of values which are adjustable at the MultiStim ECO have been compared to those with the same settings at the MultiStim SENSOR.

The desired signal combination was adjusted and visualized with an oscilloscope. The graphs were compared to each other in order to verify proper performance and substantial equivalence.

The results are as listed below:

mA	**mV**	**Output graphs compared**

mA	mV	Output graphs compared
0,2	202	Congruent
0,5	500	Congruent
0,7	712	Congruent
1,0	1000	Congruent
1,5	1520	Congruent
2,0	2040	Congruent

In addition, testing was performed per methods in the following standards:

#	Title
1.	**EN 60601-1: 1990 + A1:1993 + A2:1995 + A13:1996** Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
2.	**EN 60601-1: 2006 + AC: 2010** Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
3.	**EN 60601-1-2: 2007 + AC 2010** Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
4.	**EN 60601-1-2: 2001 + A1: 2006** Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
5.	**EN 60601-1-6: 2007 + AC:2010** Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
6.	**EN 60601-1-6: 2004** Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
7.	**EN 60601-1-8: 2007 + AC 2010** Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
8.	**EN 60601-1-8: 2004 + A1: 2006** Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
9.	**EN 60601-2-10: 2000 + A1: 2001** Medical electrical equipment -- Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
10.	**IEC 60601-2-10: 2012** Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

#	Title
11.	**EN 60601-1-2 2006 AC:2010** Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
12.	**EN 61000-4-3** Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test (IEC 61000-4-3:2006 + A1:2007 + A2:2010); German version EN 61000-4-3:2006 + A1:2008 + A2:2010
13.	**EN ISO 14971: 2012** Medical devices - Application of risk management to medical devices
14.	**EN 62366: 2008** Medical devices - Application of usability engineering to medical devices
15.	**EN 150 13485: 2012 + AC: 2012** Medical devices - Quality management systems - Requirements for regulatory purpos- es
16.	**EN 60529: 1991 + A1: 2000** Degrees of protection provided by enclosures
17.	**EN ISO 15223-1:2012** Medical devices. Symbols to be used with medical device labels, labelling and infor- mation to be supplied. General requirements
18.	**EN-980:2008** Symbols for medical device labeling

Conclusion:

The comparison between the predicate devices and the subject device of this submission as well as the results of the standard testing and bench testing demonstrates that the subject device are substantially equivalent to the predicate devices already cleared for market and therefore demonstrated to perform as effective as the legal predicate device.

The performance of the stimulation impulse generated by the subject device is at least as accurate as the impulse generated by the predicate device.