



Food and Drug Administration
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January 13, 2016

Polyganics Innovations BV
Ms. Betty IJmker
Manager QA/RA
Rozenburglaan 15A
Groningen 9727 DL
The Netherlands

Re: K152684

Trade/Device Name: Nerve Capping Device
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: December 11, 2015
Received: December 14, 2015

Dear Ms. IJmker:

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,

Carlos L. Pena -S



Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152684

Device Name

Nerve Capping Device

Indications for Use (Describe)

The Nerve Capping Device is indicated to protect a peripheral nerve end and to separate the nerve from surrounding environment to reduce the development of a symptomatic neuroma.

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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510(k) Summary of Safety and Effectiveness



Submitter:

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Date Prepared: 11 December 2015

Contact Person:

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General Provisions:

Trade Name: Nerve Capping Device
Common Name: Nerve capping device
Classification Name: Nerve cuff
21 CFR 882.5275
Product Code: JXI
Device Class: Class II
Performance Standards: None

Predicate Devices:

K050573 NEUROLAC[®] Nerve Guide (Polyganics)
K112267 NEUROLAC[®] Nerve Guide (Polyganics)
K131541 Flexible Collagen Nerve Cuff (Collagen Matrix, Inc)

Device Description:

The Nerve Capping Device is a sterile biodegradable nerve cuff composed of the bioresorbable copolyester poly(DL-lactide-ε-caprolactone). It is a tubular device with one open end and one sealed end which functions as a cap, isolating the nerve end. The capping device prevents dislocation of the stump by pulling the nerve end into the tube and suturing in the nerve within the cap. Consequently, the end of the cap will be sutured to surrounding tissue. One hole at the sealed end of the tube allows easy fixation with a suture to the surrounding tissue. The size of the product is 3cm in length, and is available in

different diameters for different sized nerves. The Nerve Capping Device is sterilized in a pouch package. The device is single-use, cannot be re-sterilized, and is a prescription product.

Indications for Use:

The Nerve Capping Device is indicated to protect a peripheral nerve end and to separate the nerve from surrounding environment to reduce the development of a symptomatic neuroma.

Summary / comparison of technical characteristics:

The Nerve Capping Device is similar in design and manufacturing, and identical in materials, packaging and sterilization method as its predicate NEUROLAC® (K050573 and K112267).

Table 1 contains a comparison of technological characteristics with the predicate devices:

Parameter	Nerve Capping Device (New Device)	NEUROLAC® (K050573)	NEUROLAC® (K112267)	Flexible Collagen Nerve Cuff (K131541)
Indications for use	The Nerve Capping Device is indicated to protect a peripheral nerve end and to separate the nerve from surrounding environment to reduce the development of a symptomatic neuroma.	The NEUROLAC® nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20mm in patients who have sustained a complete division of a nerve.	The NEUROLAC® nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20mm in patients who have sustained a complete division of a nerve.	Flexible Collagen Nerve Cuff is used for the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve in the foot to reduce the formation of symptomatic or painful neuroma.
Sterility	Sterile, SAL 10 ⁻⁶ Ethylene oxide sterilization	Sterile, SAL 10 ⁻⁶ Ethylene oxide sterilization	Sterile, SAL 10 ⁻⁶ Ethylene oxide sterilization	Sterile, SAL 10 ⁻⁶ Gamma Irradiation
Resorbable	Yes	Yes	Yes	Yes
Material	poly(DL-lactide-co-ε-caprolactone)	poly(DL-lactide-co-ε-caprolactone)	poly(DL-lactide-co-ε-caprolactone)	Type I Collagen
Source	Synthetic	Synthetic	Synthetic	Bovine tendon
Barrier function/ Permeability	Up to 10 weeks non permeable	Up to 10 weeks non permeable	Up to 10 weeks non permeable	Semi-permeable, permeable to nutrients and macromolecules
Sizes	1.5 mm ID x 3.0 cm length 2.0 mm ID x 3.0 cm length 2.5 mm ID x 3.0 cm length 3.0 mm ID x 3.0 cm length 4.0 mm ID x 3.0 cm length 5.0 mm ID x 3.0 cm length 6.0 mm ID x 3.0 cm length 7.0 mm ID x 3.0 cm length 8.0 mm ID x 3.0 cm length	4.0 mm ID x 3.0 cm length 5.0 mm ID x 3.0 cm length 6.0 mm ID x 3.0 cm length 7.0 mm ID x 3.0 cm length 8.0 mm ID x 3.0 cm length 10.0 mm ID x 3.0 cm length	1.5 mm ID x 3.0 cm length 2.0 mm ID x 3.0 cm length 2.5 mm ID x 3.0 cm length 3.0 mm ID x 3.0 cm length	2.0 mm ID x 2.5 cm length 2.5 mm ID x 2.5 cm length 3.0 mm ID x 2.5 cm length 4.0 mm ID x 2.5 cm length 5.0 mm ID x 2.5 cm length 6.0 mm ID x 2.5 cm length
Shape	Cap (tube with one closed end) 	Tube 	Tube 	Tube
Color	Transparent	Transparent	Transparent	White to Off white
Pyrogenicity	Non-pyrogenic Endotoxin ≤ 0.6 EU/device	Non-pyrogenic Endotoxin ≤ 0.18 EU/device	Non-pyrogenic Endotoxin ≤ 0.18 EU/device	Non-pyrogenic Endotoxin ≤ 0.5 EU/ml
Mechanical strength	Can be sutured	Can be sutured	Can be sutured	Can be sutured
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Biocompatible
Packaging	Polycarbonate tray and Tyvek pouch	Polycarbonate tray and Tyvek pouch	Polycarbonate tray and Tyvek pouch	Double peel package

Table 1: Comparison of technological characteristics

Performance Data:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Nerve Capping Device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The Nerve Capping Device is considered a permanent contact device: device contact exceeds 30 days.

The battery of testing included the following tests which were conducted for the predicate NEUROLAC® and leveraged for the Nerve Capping Device, except for cytotoxicity, pyrogenicity and EO residues which were conducted for the Nerve Capping Device.

The predicate test data was leveraged to support the substantial equivalence of the subject device as the device material is exactly the same for the subject and predicate device NEUROLAC® (bioresorbable copolyester poly(DL-lactide-ε-caprolactone), and the shape is tubular as the predicate device NEUROLAC® but with one closed end. The Nerve Capping Device is manufactured with an identical production process (with the only difference being the sealing step of the tip), packaging and sterilization method, and the body contact is identical.

BIOCOMPATIBILITY TEST	RESULTS	CONCLUSION
Cytotoxicity	No biological reactivity (Grade 0) was observed	No cytotoxic potential
Sensitization	No significant evidence of causing delayed dermal contact sensitization in the guinea pig	Non-sensitizing
Irritation	No erythema or edema was observed	Non-irritating
Acute systemic toxicity	Test article did not induce a significantly greater biological reaction than the control	Not considered systemically toxic
Pyrogenicity	Endotoxins were not detected	Non-pyrogenic
Hemocompatibility: Hemolysis	0.0% hemolysis was observed	Non-hemolytic
Hemocompatibility: Prothrombin Time Assay	No adverse effect on prothrombin coagulation time	Compatible with blood
Implantation/local tolerance	Relatively mild foreign body response	Relatively mild foreign body response
(Bio)degradation	After 16 months very small fragments of material were found	Biodegradable
(Sub)acute/subchronic toxicity	No toxic responses were observed	No subchronic toxicity
Genotoxicity	No statistical increase was found in the mutation frequency	Non-mutagenic
Carcinogenicity	No significant carcinogenic potential	No significant carcinogenic potential

EO and ECH residues	EO: ≤0.0016 mg/device ECH: ≤0.00045 mg/device	Residual levels acceptable
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The Nerve Capping Device complies with the biocompatibility requirements for its intended use.

Other performance testing conducted for the Nerve Capping Device:

Test	Test Method Summary	Results
<i>In vitro</i> degradation	Assessment of physical, chemical and thermal properties of the Nerve Capping Device: <ul style="list-style-type: none"> • pH testing • Dimensional testing • Weight (dry and wet state) • Tensile testing • Intrinsic viscosity • Glass temperature • Degradation products • Blue dye leak tests • Visual inspections 	The <i>in vitro</i> degradation at 37 °C behavior for Nerve Capping Device is comparable to the predicate NEUROLAC [®] , and the shape integrity will be intact for up to 10 weeks to form a barrier and separate the nerve stump from the surrounding environment. The degradation pattern is comparable to that of NEUROLAC [®] .
Usability testing	Usability and specifications of the Nerve Capping Device were assessed by providing samples to the intended end users. Their opinion and experience on the usage of the product was used to evaluate the device as design verification and validation activity to determine whether or not it meets the requirements	The overall result is that the device can be used to cover a nerve end in a fast and easy manner and that the procedure is less invasive than current used techniques. The range of dimensions from 1.5 up to 8.0 mm is sufficient and the flat tube end with fixation hole was found to be convenient to fixate the device into the tissue.
Suture retention strength	To determine the force necessary to pull a suture from the device or cause the wall of the device to fail	All samples passed the acceptance criteria and are comparable to NEUROLAC [®] regarding retention forces. The suture retention of a suture placed in the tip section is higher compared to a suture placed in the tube section.
Tip dimensional verification	To verify that the specified dimensions of the tip are met	All samples passed the acceptance criteria. The dimensions of the tip of the device (closed part) are within the tolerances as specified.

Conclusion:

The non-clinical data and the device verification and validation demonstrate that the Nerve Capping Device should perform as intended in the specified use conditions. The non-clinical data demonstrate that the Nerve Capping Device is substantially equivalent to the predicate devices.