510(k) Summary: K163446

Company Information

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Product Information

Trade Name:	AxoGen Nerve Cap
Common Name:	Nerve Cuff
Classification Name:	Nerve Cuff, 21 CFR 882.5275, Product Code JXI, Class II
Classification Panel:	Neurology

Predicate Devices

The AxoGen Nerve Cap is substantially equivalent to the following devices:

- Nerve Capping Device (Neurocap) K152684
- Surgisis Nerve Cuff (AxoGuard Nerve Connector) K031069 and K162741

Indications For Use

AxoGen Nerve Cap is indicated to protect a peripheral nerve end and to separate the nerve from surrounding environment to reduce the development of symptomatic or painful neuroma.

Device Description

The AxoGen Nerve Cap is a surgical implant that is a tubular device with one open end, one sealed end (cap) and internal channels designed to provide protection for a peripheral nerve end or stump where repair is unattainable or not desired. The device prevents dislocation of the nerve end by pulling the nerve into the tube, suturing the nerve within the cap, and securing the tab to the surrounding tissue.

AxoGen Nerve Cap is an extracellular matrix (ECM) and is fully remodeled during the healing process. The device is manufactured from processed porcine small intestinal submucosa (SIS) which is vacuum pressed prior to packaging. After hydration, the device is easy to handle, soft, pliable, non-friable and porous.

AxoGen Nerve Cap is flexible to accommodate movement of the joints and surrounding soft tissues and has sufficient mechanical strength to hold appropriately sized non-absorbable suture. It is supplied in nominal tube diameters ranging from 1.5mm up to 8mm, and a length of 13mm-38mm. AxoGen Nerve Cap is provided sterile, for single use only, and in a variety of sizes to meet clinical needs.

Performance Specifications

The performance specifications for the AxoGen Nerve Cap are described below.

Table 1
AxoGen Nerve Cap Performance Specifications

Test	Results
End Tab Shear Test**	End tab is of sufficient size to hold a class I, 8-0 USP suture as measured by lap shear of a 6-layer SIS sample with an overlap representative of the device configuration.
Suture retention strength*	The suture retention of a 4-layer SIS sample (representative of the lumen material) meets specifications (≥ 560.8 gf) after aging for 19 months and there was no loss of the ability of the material to hold suture after aging. The shelf life of the product is 18 months.
Ultimate Tensile Strength*	Ultimate Tensile Strength was not reduced with aging for 19 months. The shelf life of the product is 18 months.
Usability**	The usability study demonstrated that the design was sufficient to show that the Nerve Cap can cover the nerve, is easy to handle and suture, and the lumen did not collapse during handling.

*Test results were drawn from authorized use of a FDA Master File on well-known and characterized materials (SIS material)
**AxoGen Nerve Cap samples were used for testing

Biocompatibility

A biocompatibility evaluation in accordance with ISO 10993-1: *Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing within a Risk Management Process* was performed. The patient contact was defined as follows:

Patient Contact: Direct
Body Contact: Implantation
Type of Tissue: Tissue/Bone
Duration: Permanent (>30 days)

Table 2
Biocompatibility Testing

Biocompatibility Test	Results
Cytotoxicity	Pass Non-cytotoxic
Sensitization	Pass No evidence of sensitization
Intracutaneous/Irritation	Pass No evidence of intracutaneous reactivity
Acute Systemic Toxicity	Pass

	No mortality or evidence of acute systemic toxicity
Subchronic/chronic Systemic Toxicity	Pass Non-irritating to subcutaneous tissue No evidence of subchronic or chronic toxicity
Genotoxicity	Pass Device extracts are non-mutagenic
Implantation	Pass Irritation not greater than control materials at 24 weeks
Test results were drawn from authorized use of a FDA Master File on well-known and characterized materials (SIS material) See 510(k) K162741	

Sterilization

The AxoGen Nerve Cap is sterilized using an established ethylene oxide (EO) sterilization cycle that has been validated to a sterility assurance level (SAL) of 10^{-6} in conformance with EN ISO 11135:2014: *Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.*

Using the exhaustive extraction technique, the EO residuals for AxoGen Nerve Cap samples were verified to be less than the maximum allowable limits as defined by ISO 10993-7:2008, *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*:

Non-clinical Testing

An animal study evaluating porcine small intestine submucosa (SIS) nerve end caps in a chronic rat tibial nerve transposition (TNT) model evaluated the safety, local effects, and overall efficacy of AxoGen Nerve Caps in the reduction of painful neuroma formation. Control groups were also implanted and included a hollow tube conduit nerve cuff with an open end and a surgical control. Overall, AxoGen Nerve Caps (both Partition and Spiral) and Open Tubes nerve cuffs had similar tissue and inflammatory responses at 56 and 84 days. Furthermore, AxoGen Nerve Caps (both Partition and Spiral) were partially remodeled, but still present at 84 days post-surgery. As compared to the Surgical Controls, the Nerve Caps provided containment of nerve end and subsequent outgrowth, a reduction in nerve width measurements, and overall reduced sensitivity to mechanical stimulation, indicating a reduced likelihood of symptomatic and painful neuroma formation.

Substantial Equivalence

The AxoGen Nerve Cap is similar in intended use, design and function to the predicate device, the Polyganics Nerve Capping Device (Neurocap) cleared under 510(k) K152684. The technological similarities and differences (e.g., technological features, dimensions, materials, Intended Use, etc.) between the AxoGen Nerve Cap and the Polyganics Neurocap devices are shown in Table 3.

The primary differences include material differences, internal channels, end cap design, more sizes for the AxoGen Nerve Cap. The materials used in both devices are standard nerve cuff materials used in multiple nerve cuff products on the market today. Both devices have internal chambers/channels to reduce neuroma formation by

containing the nerve end and subsequent outgrowth. Both devices can be sutured to surrounding structures to hold the nerve cap device in place after implantation. Both devices have a variety of sizes allowing the surgeon to size match the proximal nerve stump. The difference in Intended Use (addition of pain to the Indication For Use statement) is supported by AxoGen's preclinical study. These differences in technological characteristics do not raise safety or effectiveness issues as both devices are designed to cap the end of a proximal nerve to reduce neuroma formation by containing the nerve end and subsequent outgrowth with the ability to attach the device to surrounding tissue.

Table 3
Substantial Equivalency Chart to Predicate Nerve Capping Device

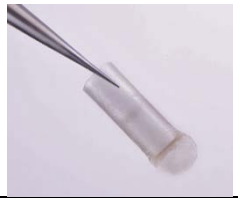
Name	**AxoGen Nerve Cap**	**Nerve Capping Device (Neurocap)**
510(k) #	This submission	K152684
Company	AxoGen Corporation	Polyganics Innovations BV
Common Name	Nerve Cuff	Nerve Cuff
Classification	Class II	Class II
Classification Product Code	JXI	JXI
Classification Panel	Neurology	Neurology
Intended Use	AxoGen Nerve Cap is indicated to protect a peripheral nerve end and to separate the nerve from surrounding environment to reduce the development of symptomatic or painful neuroma	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.
Description	AxoGen Nerve Cap is an implant manufactured from porcine small intestinal submucosa (SIS) and is in a tubular form with channels and an end cap.	Neurocap is a bioresorable peripheral nerve capping device composed of the biocompatible resorbable and synthetic polymer poly(DL-lactide)-e-caprolactone and an end cap with a hole for suturing
Device Design	Open Tube with internal channels and one end closed. 	Open Tube with one end closed.
Material Used	Porcine submucosal intestinal membrane SIS 2.0	Poly(DL-lactide)-e-caprolactone
Container	PETG Clamshell in Tyvek/Poly Chevron Pouch	Polycarbonate tray and Tyvek pouch
Single Use/Disposable	Single use only	Single use only
Sterile	Sterile SAL 10^{-6}	Sterile SAL 10^{-6}
Sterilization Method	Ethylene Oxide	Ethylene Oxide

Table 3 Substantial Equivalency Chart to Predicate Nerve Capping Device		
Name	**AxoGen Nerve Cap**	**Nerve Capping Device (Neurocap)**
510(k) #	This submission	K152684
Mechanism of Action	AxoGen Nerve Cap is designed to protect the peripheral nerve end from neurotrophic agents which can endure neuroma formation and separate the nerve from the surrounding environment to prevent adhesions of the stump to surrounding (scar) tissue which also may lead to the development of a symptomatic or painful neuroma. The material surrounding the nerve end would then remodel into a layer of soft connective tissue and function as a physical partition between the nerve and external stimuli at the nerve end. The device can be sutured to surrounding tissue with a suture through the end cap to any surrounding tissue.	Neurocap protects the peripheral nerve end from neurotrophic agents which can endure neuroma formation and separate the nerve from the surrounding environment to prevent adhesions of the stump to surrounding (scar) tissue which also may lead to the development of a symptomatic neuroma. The device can be sutured to surrounding tissue with a suture through the hole in end cap to any surrounding tissue.
Biocompatible	Biocompatible	Biocompatible
Sizes	Length includes inner lumen length (varies with nerve diameter and end cap length, up to 5 mm length) 1.5 mm ID x 13.0 mm length 1.5mm ID x 18.0 mm length 2.0 mm ID x 18.0 mm length 2.0 mm ID x 23.0 mm length 3.0 mm ID x 18.0 mm length 3.0 mm ID x 23.0 mm length 4.0 mm ID x 18.0 mm length 4.0 mm ID x 23.0 mm length 5.0 mm ID x 25.0 mm length 6.0 mm ID x 25.0 mm length 7.0 mm ID x 25.0 mm length 8.0 mm ID x 28.0 mm length 8.0 mm ID x 38.0 mm 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 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

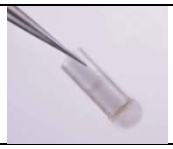
The AxoGen Nerve Cap is similar in material, design, manufacturing (including packaging and sterilization method) as the Surgisis Nerve Cuff (distributed as the AxoGuard® Nerve Connector) cleared under 510(k) K031069 and K162741. The technological similarities and differences (e.g., Indications for Use, manufacturing forming process, dimensions, material, and mechanism of use) between the AxoGen Nerve Cap and the Surgisis Nerve Cuff devices are shown in Table 4.

The Surgisis Nerve Cuff is a material predicate and not a device function predicate. The AxoGen Nerve Cuff has a different Indication For Use from the Surgisis Nerve Cuff. However both devices are used with peripheral nerve repair while achieving different purposes. There is a difference in materials, (SIS 1.0 for Surgisis Nerve Cuff versus SIS 2.0 for AxoGen Nerve Cap). Both materials are well-known and characterized materials (SIS material) and are considered equivalent. The output of the manufacturing process (device form) is different, but the manufacturing process itself is equivalent with respect to raw materials and process controls.

These differences in technological characteristics do not raise safety or effectiveness issues as both devices are designed for peripheral nerve repair and are manufactured in an equivalent manner.

Table 4
Material Substantial Equivalency

Name	**AxoGen Nerve Cap**	**Surgisis Nerve Cuff (now AxoGuard Nerve Connector)**
510(k) #	This submission	K031069 and K162741
Company	AxoGen Corporation	Cook Biotech, Inc.
Common Name	Nerve Cuff	Nerve Cuff
Classification	Class II	Class II
Classification Product Code	JXI	JXI
Classification Panel	Neurology	Neurology
Intended Use	AxoGen Nerve Cap is indicated to protect a peripheral nerve end and to separate the nerve from surrounding environment to reduce the development of symptomatic or painful neuroma.	The Surgisis Nerve Cuff is intended for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. The device is supplied sterile and is intended for one-time use.
Description	The device is an implant manufactured from porcine small intestinal submucosa (SIS) and is in a tubular form with channels and an end cap. The sizes range from diameters of 1.5-8.0 mm and lengths up to 38 mm.	The Surgisis Nerve Cuff is manufactured from porcine small intestinal submucosa (SIS) and is supplied in nominal tube diameter range of 2-7 mm and lengths up to 50 mm.
Device Design/Form	Tube with channels and end cap	Open-ended tube

Table 4 Material Substantial Equivalency		
Name	**AxoGen Nerve Cap**	**Surgisis Nerve Cuff (now AxoGuard Nerve Connector)**
510(k) #	This submission	K031069 and K162741
		
Material Used	SIS 2.0	SIS 1.0
Container	PETG Clamshell in Tyvek/Poly Chevron Pouch	PETG Clamshell in Tyvek/Poly Chevron Pouch
Single Use/Disposable	Single use only	Single use only
Sterile	Sterile SAL 10^{-6}	Sterile SAL 10^{-6}
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Mechanism of Action	AxoGen Nerve Cap is designed to protect the peripheral nerve end from neurotrophic agents which can endure neuroma formation and separate the nerve from the surrounding environment to prevent adhesions of the stump to surrounding (scar) tissue which also may lead to the development of a symptomatic or painful neuroma.. The material surrounding the nerve end would then remodel into a layer of soft connective tissue and function as a physical partition between the nerve and external stimuli at the nerve end. The device can be sutured to surrounding tissue with a suture through the end cap to any surrounding tissue.	The Surgisis Nerve Cuff is designed to be a flexible, resorbable and semipermeable tubular membrane matrix to provide a protective environment for peripheral nerve repair after injury and to create a conduit for axonal growth across a nerve gap
Manufacturing Method	Manufacturing results in a closed tube with channels	Manufacturing results in a simple round open-ended tube
Biocompatible	Biocompatible	Biocompatible

Conclusion

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