April 7, 2023

AxoGen Corporation
Jonathan White
Senior Regulatory Affairs Specialist
13631 Progress Blvd, Ste 400
Alachua, Florida 32615-9409

Re: K223640
Trade/Device Name: Axoguard HA+ Nerve Protector (AGHA12); Axoguard HA+ Nerve Protector (AGHA22); Axoguard HA+ Nerve Protector (AGHA24); Axoguard HA+ Nerve Protector (AGHA36); Axoguard HA+ Nerve Protector (AGHA48)
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: December 5, 2022
Received: December 5, 2022

Dear Jonathan White:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yen-chih Lin -S

Digitally signed by Yen-chih Lin -S
Date: 2023.04.07 14:28:21 -04'00'

for Adam Pierce
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223640

Device Name
Axoguard HA+ Nerve Protector (AGHA12); Axoguard HA+ Nerve Protector (AGHA22); Axoguard HA+ Nerve Protector (AGHA24); Axoguard HA+ Nerve Protector (AGHA36); Axoguard HA+ Nerve Protector (AGHA48)

Indications for Use *(Describe)*
Axoguard HA+ Nerve Protector is indicated for the management of peripheral nerve injuries where there is no gap.

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: K223640

1. Submitter

Name:	Axogen Corporation 13631 Progress Blvd, Ste 400 Alachua, FL 32615
Contact Person:	Jonathan White
Contact Title:	Senior Regulatory Affairs Specialist
Phone (office):	386-462-6800
Email:	ra@axogeninc.com

Date Prepared:	December 5, 2022

2. Device Information

Trade Name:	Axoguard HA+ Nerve Protector
Common Name:	Nerve Cuff
Classification Name:	Nerve Cuff
Regulatory Class:	Class II
Product Code:	JXI
Regulation Number:	21 CFR 882.5275

3. Predicate Device

Axoguard HA+ Nerve Protector is substantially equivalent to the following device:

- Axoguard Nerve Protector K132660

4. Device Description

The Axoguard HA+ Nerve Protector is a surgical implant that provides non-constricting protection for peripheral nerves. Axoguard HA+ Nerve Protector is designed to be an interface between the nerve and the surrounding tissue. Axoguard HA+ Nerve Protector is comprised of an extracellular matrix (ECM) and is fully remodeled during the healing process. The lubricant coating on Axoguard HA+ Nerve Protector is composed of sodium hyaluronate and sodium alginate. When hydrated, the lubricant coating reduces friction between the nerve and the surrounding tissue. Axoguard HA+ Nerve Protector is flexible to accommodate movement of the joint and associated tendons and has sufficient mechanical strength to hold sutures. Axoguard HA+ Nerve Protector is provided sterile, for single use only, and in a variety of sizes to meet surgeons' needs.

5. Indications for Use

Axoguard HA+ Nerve Protector is indicated for the management of peripheral nerve injuries where there is no gap.

6. Comparison of Technological Characteristics with the Predicate Device

Axoguard HA+ Nerve Protector is similar in intended use and indications for use, design, principle of operation, and material (ECM base membrane) as Axoguard Nerve Protector. **Table 6-1** below summarizes the comparison between Axoguard HA+ Nerve Protector and its predicate.

Table 6-1: Device Technological Characteristics Comparison Summary

Name	**Axoguard HA+ Nerve Protector**	**Axoguard Nerve Protector (Predicate)**
510(k)#	K223640	K132660
Manufacturer	Axogen Corporation	Cook Biotech Inc.
Common Name	Nerve Cuff	Nerve Cuff
Device Class	Class II	Class II
Classification Name and Number	Nerve Cuff; 21 CFR 882.5275	Nerve Cuff; 21 CFR 882.5275
Classification Product Code	JXI	JXI
Prescription/Over the Counter Use	Rx only	Rx only
Intended Use	Designed to be an interface between the peripheral nerve and the surrounding tissue.	Designed to be an interface between the peripheral nerve and the surrounding tissue.
Indications for Use	Axoguard HA+ Nerve Protector is indicated for the management of peripheral nerve injuries where there is no gap.	Axoguard Nerve Protector is indicated for the repair of peripheral nerve injuries in which there is no gap or where a gap closure is achieved by flexion of the extremity. The device is provided sterile and intended for one-time use.
Dimensions	Width (cm) / Length (cm) / Area (cm^2): 1 / 2 / 2; 2 / 2 / 4; 2 / 4 / 8; 3 / 6 / 18; 4 / 8 / 32	1.5 - 10 mm (diameter) x 1- 5 cm length
Material	Porcine small intestinal submucosa (SIS) extracellular collagen matrix (ECM), sodium hyaluronate, and sodium alginate	Porcine small intestinal submucosa (SIS) extracellular collagen matrix (ECM)
Configuration	Flat sheet	Curled sheet
Sterile/Single Use	Sterile; single use	Sterile; single use
Sterility / Sterilization Method	SAL 10^{-6} / Ethylene Oxide	SAL 10^{-6} / Ethylene Oxide

7. Performance Data

The following performance data are provided in support of the substantial equivalence determination: performance testing including coefficient of friction, suture retention, ultimate tensile strength, bubble emission (packaging), seal strength (packaging) and end-user validation. These evaluations demonstrate that the device meets the requirements for its intended use. **Table 7-1** summarizes the testing performed for the Axoguard HA+ Nerve Protector.

Table 7-1: Axoguard HA+ Nerve Protector Testing Summary

Test	Test Method Summary	Summary Result
Coefficient of Friction	Aged and unaged devices were evaluated for their static coefficient of friction (lubricity) based on ASTM D1894-14.	Test articles met the acceptance criteria.
Suture Retention Strength	Aged and unaged devices were evaluated for their suture retention strength by placing a suture through the devices and the force required to pull free was measured, based on ANSI/AAMI/ISO 7198.	Test articles met the acceptance criteria.
Ultimate Tensile Strength	Aged and unaged devices were evaluated for their ultimate tensile strength by placing the devices between two grips. The separation force required resulting in device failure was measured, based on ASTM D882-18.	Test articles met the acceptance criteria.
Bubble Emission (Packaging)	Aged and unaged devices underwent ethylene oxide sterilization, and visual inspection prior to bubble leak testing. The test articles underwent evaluation in accordance with ASTM F2096-11(2019).	Test articles met the acceptance criteria.
Seal Strength (Packaging)	Aged and unaged devices underwent ethylene oxide sterilization, and visual inspection prior to seal strength testing. The test article sample sets were subjected to seal strength testing in accordance with ASTM F88/F88-21.	Test articles met the acceptance criteria.
Endotoxin	Test article extracts were evaluated for bacterial endotoxins using the Kinetic-Turbidimetric test method in accordance with USP 43- NF38, General Chapter <85>, USP43-NF38, General Chapter <161> and ANSI/AAMI ST72.	Test article extracts met USP requirement.
End-user Validation	Surgeon end-users implanted the subject device in a simulated surgical environment to assess device ease of use, and its conformance to user needs and its intended use.	Test articles met the acceptance criteria.

Biocompatibility

Biocompatibility endpoints for cytotoxicity, irritation, sensitization, material mediated pyrogenicity, acute systemic toxicity, and genotoxicity for the subject device in compliance with ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a

risk management process (FDA Recognized Consensus Standard 2-258) were assessed. Additionally, two non-clinical GLP studies evaluating the effects and biocompatibility of the device on the nerve and the surrounding muscle tissue were performed. All necessary endpoints according to the standard were met.

9. Substantial Equivalence

The non-clinical data support the safety of the device and demonstrate that the Axoguard HA+ Nerve Protector performs as intended in its specified use conditions, and is substantially equivalent to its predicate device and does not raise different questions of safety and effectiveness.