November 7, 2019

Stimwave Technologies Inc.
Elizabeth Greene
Chief Compliance Officer
1310 Park Central Boulevard South
Pompano Beach, Florida 33064

Re: K191466
Trade/Device Name: SandShark Injectable Anchor (SIA) System
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted Spinal Cord Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZB
Dated: August 9, 2019
Received: August 9, 2019

Dear Elizabeth Greene:

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,

Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191466

Device Name
SandShark Injectable Anchor (SIA) System

Indications for Use *(Describe)*
The SandShark Injectable Anchor (SIA) System is intended to be an accessory to the stimulator component of the Stimwave Freedom Spinal Cord Stimulator (SCS) System to secure the stimulator to the fascia or interspinous/supra-spinous ligament.

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
PRAStaff@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."

510(k) Summary

for

SandShark Injectable Anchor (SIA) System

1. Submission Sponsor

Stimwave Technologies Incorporated
1310 Park Central Boulevard South
Pompano Beach
FL, 33064
USA
Phone: 800.965.5134
Fax: 800.965.5134
Contact: Elizabeth Greene, Chief Compliance Officer

2. Date Prepared

May 31, 2019

3. Device Identification

Trade/Proprietary Name:	SandShark Injectable Anchor System
Classification Name:	Stimulator, Spinal-Cord, Implanted (Pain Relief)
Classification Regulation:	882.5880
Product Code:	GZB
Device Class:	Class II
Classification Panel:	Neurology

4. Legally Marketed Predicate Device(s)

SandShark Injectable Anchor (SIA) System (K172644)

5. Device Description

The Stimwave Technologies Incorporated (Stimwave) SandShark Injectable Anchor (SIA) System is used to fixate the Stimwave Freedom Stimulator to surrounding tissue. The System is comprised of a carbothane anchor (SandShark Anchor) that is transferred onto the deployment handle (SandShark Injectroducer) with the Loading Rod and Loading Base. The SIA System is provided sterile. The SandShark Injectroducer is used to deploy the SandShark Anchor onto the Stimulator.

SandShark Injectable Anchor (SIA) System	
Injectroducer	An acrylonitrile butadiene styrene (ABS) handle and cannula (stainless steel 304V, KR01 Phillips K-Resin) anchor deployment device that is used to secure the SandShark Anchor onto the stimulator to the fascia or interspinous/supra-spinous ligament. Identical to K172644.
SandShark Anchor	A carbothane (80A) anchor that is deployed by the Injectroducer onto the stimulator securing the device to the fascia or interspinous/supra-spinous ligament. Four (4) SandShark Anchors are provided in the SIA System, pre-loaded onto the Loading Rod. Identical to K172644.
Loading Rod	An assembly that is used with the Loading Base to transfer the SandShark Anchor onto the cannula of the Injectroducer. The handle is constructed of ABS and the rod is stainless steel 304V. Identical to K172644.
Loading Base	An ABS base that holds the Loading Rod in place while transferring the SandShark Anchor onto the cannula of the Injectroducer. The design has been updated to be hand-held; no change in material.

6. Indication for Use Statement

The SandShark Injectable Anchor (SIA) System is intended to be an accessory to the stimulator component of the Stimwave Freedom Spinal Cord Stimulator (SCS) System to secure the stimulator to the fascia or interspinous/supra-spinous ligament.

7. Substantial Equivalence Discussion

The following table compares the Stimwave SIA System to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A. Comparison of Characteristics

Comparator	Stimwave SandShark Injectable Anchor (SIA) System (K172644)	Stimwave SandShark Injectable Anchor (SIA) System (This submission)
Product Code	GZB	Same as K172644
Regulation No.	882.5880	Same as K172644
Regulation Name	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Same as K172644
Intended Use	Accessory for securing a spinal cord stimulator to surrounding tissue	Same as K172644
Implant Site	Fascia or inter-spinous/supra-spinous ligament	Same as K172644
Environmental Use	Hospital or Ambulatory Surgical Center Only	Same as K172644
Intended Clinician	Orthopedic, Neurosurgeon, Anesthesiologist	Same as K172644
Anchor Material	Carbothane 80A	Same as K172644
Cannula Material	Stainless Steel 304V	Same as K172644
Anchor Length	1.5 inch	Same as K172644
Anchor Outer Diameter	0.087 inch	Same as K172644
Loading Base	Table-top design	Hand-held design
Method of Introduction	Percutaneous and Anchor Incision	Same as K172644

Comparator	Stimwave SandShark Injectable Anchor (SIA) System (K172644)	Stimwave SandShark Injectable Anchor (SIA) System (This submission)
Tissue Contact	Yes	Same as K172644
Sterilization	Ethylene Oxide (EO)	Same as K172644
Labeling	Labeled as Sterile, Single Use, Prescription Device	Same as K172644
Sterile	Yes - ethylene oxide	Same as K172644
Single-Use	Yes	Same as K172644
Shelf Life	1 year	Same as K172644
Complies with ISO 10993-1	Yes	Same as K172644
Safety Testing Passed	Yes	Same as K172644

(*) asterisk denotes that formulas were used for the calculations.

8. Biocompatibility Data

The materials, construction and intended use of the SIA System are identical to the predicate device, and have a long history of safety with respect to biocompatibility, thus the biological safety testing of the SIA System is leveraged from K172644. The biological safety of the SandShark Anchor was evaluated in accordance to ISO 10993-1:2009, guidance document *Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and Blue Book Memorandum G95-1 *Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing*. Under these, for the stated indications for use, the device was classified as a (C), implant device in contact with tissue/bone. The results for the biocompatible testing for cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, genotoxicity, implantation (4, 8, and 13 weeks), subacute and subchronic toxicity, chronic toxicity, carcinogenicity, extractables and leechables demonstrated no negative impacts from the materials that are used in the SIA System. The SIA System meets biological safety and compatibility requirements of ISO 10993-1:2009 and Blue Book Memorandum G95-1.

9. Non-Clinical Performance Data

The SIA System was tested to verify that the performance meets the system design requirements as well as all applicable voluntary standards. The SIA System complies with all design requirements and applicable voluntary standards.

AAMI ANSI ISO 14708-3:2008 – For protection from temperature change including shipping and storage temperature ranges, the SIA System was functional, receiving a safe rating following post visual inspection and passed the change of temperature testing performed as specified by AAMI ANSI ISO 14708-3:2008. For atmospheric pressure change, the SIA System was functional following post testing functionality inspection and passed atmospheric pressure change testing as specified by AAMI ANSI ISO 14708-3:2008. The testing is leveraged from K172644 and is directly applicable for demonstration of device safety and efficacy as the packaging, mode of action, and materials remain the same. The design modification to the Loader Base does not impact the outcome of the leveraged tests for safety and effectiveness.

Stimwave completed a number of tests for the SIA System that demonstrates substantial equivalence to the legally marketed predicate device. The SIA System meets all the requirements for overall design, sterilization, and biocompatibility confirms that the output meets the design inputs and specifications through leveraged or new testing described in this submission. The SIA System passed all testing stated above as shown by the acceptable results obtained. The updated design of the Loading Base does not impact device performance, and thus, demonstrates continued safety and efficacy compared to the predicate device. The inclusion of secondary contract suppliers for the SIA System demonstrates no impact to established safety and efficacy.

10. Clinical Performance Data

There was no clinical testing required to support the medical device, as the indications for use are equivalent to the legally marketed predicate device. These types of devices, including the legally marketed predicate device, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to legally marketed predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. The SIA System has the same intended use as the legally marketed predicates device. Performance testing data leveraged from K172644 verifies that the SIA System complies with all applicable voluntary standards such as AAMI ANSI ISO 14708-3. The SIA System also meets the design requirements where no applicable standard could be used. This includes leveraged anchor durability testing, as well as biocompatibility and sterilization validation of the SIA System. There were no recognized performance standards for this device. There was no clinical testing performed on this device since performance testing demonstrated similar performance as the legally marketed predicate device, and materials for the SIA System are the same as the legally marketed predicate device. The updated design of the Loading Base does not impact device performance, and thus, demonstrates continued safety and efficacy compared to the predicate. The inclusion of secondary contract suppliers for the SIA System demonstrates no impact to established safety and efficacy.

It has been shown in this 510(k) submission that the difference between the SIA System and the legally marketed predicate device do not raise any questions regarding its safety and effectiveness as compared to legally marketed predicate device. The SIA System, as designed and manufactured, is determined to be substantially equivalent to the referenced legally marketed predicate device.