June 29, 2023

TeDan Surgical Innovations, Inc.
Lynne Davies
Vice President, Regulatory Affairs and Quality Assurance
12320 Cardinal Meadow Dr.
Ste. 150
Sugar Land, TX 77478

Re: K231691
Trade/Device Name: Phantom XL Insulated Dilators
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: II
Product Code: PDQ
Dated: June 7, 2023
Received: June 9, 2023

Dear Lynne Davies:

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,

Patrick Antkowiak -S

for
Jay Gupta
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)*
not assigned

Device Name
Phantom XL Insulated Dilators

Indications for Use *(Describe)*

Phantom XL Insulated Dilators are indicated for use during surgery of the spine to deliver an electrical stimulus to the tissues and nerves at the operative site, to assist in locating those nerves at risk during the surgical procedure.

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

Submitter:	TeDan Surgical Innovations, Inc. 12320 Cardinal Meadow Drive Suite 150 Sugar Land, Texas 77478 USA
Contact Person	Lynne Davies Vice President, Regulatory Affairs and Quality Assurance
Telephone:	713-726-0886
Submission Date:	June 7, 2023
Device Name:	Phantom XL Insulated Dilators
Common Name:	Needle electrode
Regulatory Class:	II
Classification Name:	Neurosurgical nerve locator, 21 CFR 874.1820 (PDQ)

A. Predicate Device

The predicate device is the Phantom XL Insulated Dilators (K140088) also manufactured by TeDan Surgical Innovations, Inc.

B. Device Description

TSI's Phantom XL Insulated Dilators are used as instruments to deliver electrical stimulation to tissue during intraoperative neurological monitoring. Phantom XL Insulated Dilators are available in monopolar configuration and four diameter sizes. They are supplied sterile, are non-pyrogenic, and are intended for single use only.

C. Indications for Use

TSI's Phantom XL Insulated Dilators are indicated for use during surgery of the spine to deliver an electrical stimulus to the tissues and nerves at the operative site, to assist in locating those nerves at risk during the surgical procedure.

D. Comparison of Technological Characteristics with the Predicate Device

The following technological differences exist between the subject and predicate devices:

- Change in packaging from backer card/Tyvek pouch/Shelf Box configuration to preformed tray sealed in Tyvek Lid placed in Shelf Box
- Extended shelf life from 2 years to 5 years

Device Name	**Predicate Device Phantom XL Insulated Dilators K140088**	**Subject Device Phantom XL Insulated Dilators K231619**
Manufacturer	TeDan Surgical Innovations	TeDan Surgical Innovations
510(k) number	K140088	K231619
Regulation	21CFR 882.1350, (GZX) and 21 CFR 874.1820 (PDQ)	21 CFR 874.1820
Review panel	Neurology	Neurology
Product code	Initially filed as GXZ, subsequently changed to PDQ	PDQ
Regulation description	Needle electrode	Surgical nerve stimulator/locator.
Classification	Class II	Class II
Indication for use and Intended use	Phantom XL Insulated Dilators are indicated for use during surgery of the spine to deliver an electrical stimulus to the tissues and nerves at the operative site, to assist in locating those nerves at risk during the surgical procedure.	Phantom XL Insulated Dilators are indicated for use during surgery of the spine to deliver an electrical stimulus to the tissues and nerves at the operative site, to assist in locating those nerves at risk during the surgical procedure.
Biocompatibility	Compliant with ISO 10993 for contact of limited duration	Compliant with ISO 10993 for contact of limited duration
Sterile	Yes; EtO	Yes; EtO
Single Use	Yes	Yes
Shelf Life	2 years	5 years

Device Name	Predicate Device Phantom XL Insulated Dilators K140088	Subject Device Phantom XL Insulated Dilators K231619
Principle of Operation	Used as instrument to deliver electrical stimulation to tissue during neurological monitoring	Used as instrument to deliver electrical stimulation to tissue during neurological monitoring
Polarity of stimulation	Monopolar	Monopolar
Exposed area of stimulation	Tissues and nerves at the operative site selected by the user	Tissues and nerves at the operative site selected by the user
Electrical Safety	Compliant with IEC 60601-1	Compliant with IEC 60601-1
Packaging	Product is loaded into backer cards and sealed in a Tyvek Pouch; Pouch is placed in Shelf Box; compliant with applicable ASTM standards	Product is loaded into preformed tray and sealed in a Tyvek Lid; Tray is placed in Shelf Box; compliant with applicable ASTM standards

E. Performance Data

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

Type of change	Description of Tests
Packaging	ASTM F1886:2016, Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection ASTM F2096-11, Standard test method for detecting Gross Leaks in Packaging by internal Pressurization ASTM F88/F88M-21,2021, Standard Test Method for Seal Strength of Flexible Barrier Materials (Dupont Medical Packaging, Description of Documents Supporting the Compliance of Tyvek to ISO 11607 Standard) ASTM D4169:2022, Standard Practices for Performance Testing of Shipping Containers and Systems ISTA 3A: 2018, Packaged-Products for Parcel Delivery System Shipments 70kg (150lb) or Less ISO 11607-2:2019, Packaging for terminally sterilized medical devices-Part 2: Validation requirements for sealing and assembly processes ISO 16269-6:2014, Statistical interpretation of data – Part 6: Determination of statistical tolerance intervals
Expiration Date	ASTM F1980; 2021, Guide to Accelerated Aging of Sterile Medical Device Packages

Type of change	Description of Tests
Sterilization	ISO 11607-1:2019, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems AAMI/ISO TIR16775: 2014, Technical Information Report, Packaging for terminally sterilized medical devices-Guidance on the application of ISO 11607-1 and ISO 11607-2 AAMI TIR28:2016, Product adoption and process equivalency for ethylene oxide sterilization ANSI/AAMI ST67:2019 – Sterilization of health care products – Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled sterile ANSI/AAMI/ISO 11135:2014, Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices– Part 1, Sterilization of health care products, Ethylene oxide, Part 1 ANSI/AAMI ST72; 2019, Bacterial Endotoxins-Test methods, routine monitoring, and alternatives to batch testing

Additional verification and validation testing were completed in accordance with the company's Design Control process in compliance with 21 CFR Part 820.30, including the following:

1. Bench testing for sterility in compliance with the standards cited above
2. Bench testing for new expiration dating in compliance with the standards cited above
3. Bench testing for packaging integrity in compliance with the standards cited above

F. Conclusion

Potential risks were identified according to the ISO 14971 Standard. The risks were analyzed with regard to risk/benefit category and mitigations were implemented and tested as part of the performance testing described above for the changes submitted. No new risks were identified for the modifications to the devices. All risk mitigations were satisfactorily verified and validated in compliance with the company's Design Control Process. Where there were differences from the predicate, these were shown not to result in any new issues of safety or effectiveness according to the performance data submitted. Therefore, the non-clinical performance data provided demonstrates that the TSI Phantom XL Dilators are safe for use perform comparably to the predicate device that is currently marketed for the same intended use.