DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 25, 2014

TeDan Surgical Innovations, LLC
Ms. Dionicia Reblando
12615 W. Airport Blvd., Suite 200
Sugar Land, TX 77478

Re: K140088
Trade/Device Name: Phantom XL Insulated Dilators
Regulation Number: 21 CFR 874.1820
Regulation Name: Neurosurgical Nerve Locator
Regulatory Class: Class II
Product Code: PDQ
Dated: August 25, 2014
Received: August 27, 2014

Dear Ms. Reblando:

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" (21CFR 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, Ph.D, M.S.
Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140088

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.

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510(k) Summary

Assigned 510(k) number:	K140088
Company:	TeDan Surgical Innovations, LLC 12615 W Airport Blvd, Suite 200 Sugar Land, TX USA 77478 Phone: 650-631-4515 Fax: 650-631-4555
Contact:	Dionicia Reblando Phone: 858-472-5160 Email: jreblando@yahoo.com
Date Prepared:	July 23, 2014
Proprietary Names:	Phantom XL Insulated Dilators
Classification Name:	Needle electrode
Classification:	21 CFR 882.1350, Class II, Product Code GXZ
Predicate Device:	K110419 AVS® ARIA Probe Dilators
Device Description:	Phantom XL Insulated Dilators are used as instruments to deliver electrical stimulation to tissue during intraoperative neurological monitoring. The Phantom XL Insulated Dilators are available in monopolar configuration and four diameter sizes (8, 13, 18, 22 and 22mm Grooved). They are supplied sterile, are non-pyrogenic, and are intended for single use only. The 8 mm dilators are made of stainless steel and are visible under fluoroscopy, while the remaining sizes are made of aluminum alloy and are radiolucent.
Intended Use:	Phantom XL Insulated Dilators are indicated for use during surgery of the spine to deliver an electrical stimulus to the tissue and nerves at the operative site, to assist in locating those nerves at risk during the surgical procedure.
Technological Comparison to Predicate Device:	Phantom XL Insulated Dilators are similar to the predicate device. Both are needle electrodes used to deliver an electrical stimulus to tissues and nerves at the operative site. Additionally, both use the same fundamental scientific technology and principle of operation. Performance test results confirm that design, material, and

sterilization differences do not pose new issues of safety or effectiveness. Both devices attain a minimum Sterility Assurance Level of 1 X 10^{-6}

Performance Testing:

ELECTRICAL SAFETY TESTING

Electrical safety testing was performed for the Phantom XL Insulated Dilators in accordance with the standard: IEC 60601-1 (2012) Ed 3.1; Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. The following applicable tests were performed:

1. Impedance of current carrying connections. This test was performed to demonstrate that the Phantom XL Insulated Dilators have sufficiently low impedance so that they will not interfere with any stimulator signal passed through them.
2. Dielectric Strength test. This test was performed to demonstrate that the insulated portions of the Phantom XL Insulated Dilators are sufficiently separated from the conductive portions to prevent any stimulator signal from reaching any part of the Phantom XL Insulated Dilators except the intended delivery point.
3. Temperature test. This test was performed to demonstrate that the Phantom XL Insulated Dilators will not introduce any additional heating to the patient as part of the stimulation process.
4. Waveform capture. Waveform of the stimulator output was capture on an oscilloscope in 3 modes of operation. The tests were performed to demonstrate that the Phantom XL Insulated Dilators will not significantly alter the waveform.

The Phantom XL Insulated Dilators met applicable requirements set forth in the referenced standard. Electrical Safety Report 261304 for IEC 60601-1 compliance, is provided in Attachment 4.

ELECTROMAGNETIC COMPATIBILITY

The Phantom XL Insulated Dilators underwent electromagnetic compatibility (EMC) testing in accordance with IEC 60601-1-2:2007, Medical electrical equipment – Part 1-2:2007 General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. The following applicable tests were performed:

1. Emissions tests
2. Immunity tests

The above tests were conducted to evaluate and verify that the Phantom XL Dilators/accessories do not impact the emission

profile or increase the sensitivity to adverse conditions of electrical stimulus and medical monitoring equipment.

The Phantom XL Insulated Dilators met applicable requirements set forth in the referenced standard. EMC Test Report Number 2014 261304 EMC for IEC 60601-1-2:2007 compliance, is provided in Attachment 5.

BIOCOMPATIBILITY

The biocompatibility tests for the Phantom XL Dilators were selected in accordance with blue book memorandum G95-1 entitled Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices — Part 1: Evaluation and Testing". Biocompatibility tests were conducted in compliance with U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR 58. The Table below summarizes the results of the biocompatibility testing.

Test	Results	Conclusions
Cytotoxicity-ISO Elution Method (ISO 10993-5:2009)	No evidence of causing lysis or toxicity. Reactivity is less than grade 2	Non-Cytotoxic. (acceptance criteria: biological reactivity must be less than or equal a grade 2
ISO Intracutaneous Study- Irritation (ISO 10993-10:2010)	Observations for erythema and edema. The difference between each test article extract overall mean score and corresponding control extract overall mean score was 0.0 and 0.2	Non-irritant. (acceptance criteria: the difference between the test extract overall mean score and corresponding control overall mean score is 1.0 or less).
ISO Guinea Pig Maximization Sensitization Test (ISO 10993-10:2010)	The test article extracts showed no evidence of causing delayed dermal contact sensitization	Non-Sensitizer
ISO Systemic Toxicity (acute) (ISO 10993-11:2010	There was no mortality or evidence of systemic toxicity from the extracts	Non-Toxic (acute-systemic)

STERILIZATION, BACTERIAL ENDOTOXIN AND ETHYLENE OXIDE RESIDUALS

A sterilization validation of the Phantom XL insulated dilators based on the requirements of ANSI/AAMI/ISO 11135-1:2007 was completed to assure a minimum Sterility Assurance Level of $1X10^{-6}$. The Table below summarizes the results of the Bacterial Endotoxin and the residual levels

Test	Results	Conclusions
Bacterial Endotoxin	0.720 EU/Device 0.880 EU/Device < 0.200 EU/Device'	a. The results passes FDA criteria for both: medical device – maximum of 20 EU/device b. device contacting cerebrospinal fluid-maximum of 2.15 EU/device Note: This device does not contact cerebrospinal fluid.
Ethylene Oxide residual	Range: <0.12 – 0.15 mg/device	Pass the requirements of 4 mg/device
Ethylene Chlorohydrin residual	Range: <0.10 - <0.15 mg/device	Pass the requirements of 9 mg/device