April 26, 2026

Tedan Surgical Innovations
Arya Monticino-Larsen
RAQA Engineer
12320 Cardinal Meadow Dr.
Suite 150
Sugar Land, Texas 77478

Re: K253580
Trade/Device Name: Sterile Insulated Dilators, 5, 10, 16mm (MDT-0442S); Sterile, Insulated Dilator, 20mm (MDT-0469S)
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: PDQ
Dated: March 26, 2026
Received: March 27, 2026

Dear Arya Monticino-Larsen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JAY R. GUPTA -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253580

Please provide the device trade name(s).

Sterile Insulated Dilators, 5, 10, 16mm (MDT-0442S);
Sterile, Insulated Dilator, 20mm (MDT-0469S)

Please provide your Indications for Use below.

Spine surgery for sequential dilation and to deliver an electrical stimulation to the tissue and nerves at the operative site to assist in locating those nerves at risk during the surgical procedure. Navigated ø5mm Insulated Dilator is intended to be used during spinal surgery to assist the surgeon in precisely establishing the desired access trajectory. Navigated ø5mm Insulated Dilator is specifically designed for use with Medtronic Stealth™ Systems, where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR-based model, or fluoroscopy images.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

26-March-2026

Company: TeDan Surgical Innovations, Inc.
12320 Cardinal Meadow Drive
Suite 150
Sugar Land, Texas 77478 USA
Telephone: (713) 726-0886

Contact: Arya Monticino-Larsen (Primary)
RAQA Engineer
Email: amonticino@tedansurgical.com

Lynne Davies (Alternate)
VP of RAQA
Email: ldavies@tedansurgical.com

Device Name: Sterile Insulated Dilators, 5, 10, 16mm (MDT-0442S); Sterile Insulated Dilator, 20mm (MDT-0469S)

Common Name: Needle Electrode, Navigated Instrument

Classification Name: Neurosurgical nerve locator (21 CFR §874.1820)

Regulatory Class: Class II

Product Code PDQ

A. Predicate Device

The legally marketed predicate devices are identified as below:

Predicate	Primary Predicate	Reference Device
Device Name	Phantom XL Insulated Dilators	CD Horizon™ Navigated Instruments
510(k) Number	K231691	K182121
FDA Regulation	21 CFR §882.1350, 21 CFR §874.1820	21 CFR §882.4560
FDA Product Code	GXZ, PDQ	OLO
Manufacturer	TeDan Surgical Innovations, Inc.	Medtronic Sofamor Danek USA, Inc.

These predicates have not been subject to a design-related recall.

B. Device Description

The TeDan Surgical Innovations, Inc. (TSI) Insulated Dilators are used as instruments to deliver electrical stimulation to tissue during intraoperative neurophysiological monitoring (IONM). The Insulated Dilators are available in four diameter sizes (5, 10, 16, & 20mm). They are supplied sterile, (single-use only) three (3) dilators per tray (MDT-0442S) or one (1) dilator per tray (MDT-0469S), one (1) tray per box. They are non-pyrogenic and are intended for single use only. The ø5mm dilator is made of stainless steel. The 10, 16, & 20mm dilators are made of aluminum alloy. The TSI Insulated Dilators are intended to incrementally dilate the surgical site. Product is intended to be used by trained surgeons. The ø5mm Insulated Dilator (MDT-0466) may be used as a navigated surgical instrument with Medtronic Stealth™ Systems (Medtronic computer assisted surgery system) to track the Insulated Dilator in the surgical field.

C. Indications for Use

The TeDan Surgical Innovations, Inc. (TSI) Sterile Insulated Dilators

Spine surgery for sequential dilation and to deliver an electrical stimulation to the tissue and nerves at the operative site to assist in locating those nerves at risk during the surgical procedure. Navigated ø5mm Insulated Dilator is intended to be used during spinal surgery to assist the surgeon in precisely establishing the desired access trajectory. Navigated ø5mm Insulated Dilator is specifically designed for use with Medtronic Stealth™ Systems, where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR-based model, or fluoroscopy images.

Phantom XL Insulated Dilators

Spine surgery for sequential dilation and 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.

The indications for use statement of the subject device is substantially equivalent to the primary predicate device, with additional language provided for clarifying how the device is used with the Medtronic Stealth™ Systems. The clarifying language and differences in indications for use do not change the intended use as a neurosurgical nerve locator, nor raise new questions of safety or effectiveness, as demonstrated by results of the risk-based verification and validation testing.

D. Comparison of Technological Characteristics with Predicate Device

The use of unidirectional electrical stimulation for neuromonitoring is the technological principle for both the subject and predicate devices. At a high level, the subject and predicate devices are based on the following same technological elements:

- Sequential dilation – used to incrementally increase the dilation size of the access site
- Dilators connected to a stimulation clip to allow for transmission of electrical stimulus into the tissue to collect nerve location feedback
- Dilator has unidirectionally designed conductive surface characterized by a distal conductive surface and a proximal conductive collar
- Use of the dilators to aid in insertion of retractor blades into the surgical site to reduce risk of tissue/nerve pinching

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

Attribute	Subject Device Sterile Insulated Dilators	Primary Predicate Device Phantom XL Insulated Dilators
Materials of Construction		
Initial dilator base material	17-4 PH H900	304 SST
Distal exposed surface		
Distal Shape	Oval/Rounded Rectangle	Triangle
Electrode Surface Area	20-25 mm^2	7.5 mm^2
Dilator Body		
Body Outer Diameters	5, 10, 16, & 20 mm	7, 8, 12, 13, 15, 18, & 22 mm
Wall thickness	0.27-2.55 mm	1.45-2.50 mm
Length	222.00-295.50 mm	195-255
Geometry	- ø5mm dilator - Solid design with tapered tip; exposed proximal end features a square end and a notch to mate with system components - ø20mm dilator - Features grooves down its sides	All dilators are uniformly round for the majority of the length with a tapered distal tip. There is an exposed segment proximally with a knurled insulated region at the proximal end.
System Compatibility		
Medtronic Stealth™ Systems, associated surgical instrumentation and accessories	Compatible	Not compatible

E. Performance Data

The Sterile Insulated Dilators presented in this Traditional 510(k) have been verified and validated according to TeDan Surgical Innovations' 21 CFR Part 820.30-compliant Design Control procedures. Non-clinical testing to confirm device performance for its intended use is summarized as follows:

Test	Test Method Summary	Results/Conclusions
Force Testing	Force testing was conducted to verify that the changes to material and geometry can withstand the forces experienced while dilating the psoas.	Results verify that the dilators meet force requirements. All acceptance criteria were met.
Tolerance Stack	Tolerance stack analysis was performed to verify that the Sterile Insulated Dilators mate appropriately with compatible components.	Results verify that the dilators meet requirements to mate appropriately with compatible components.
Human Cadaver Study	A human cadaver study was performed to validate that the dilators, when used as an integrated system with the Medtronic Stealth™ Systems navigation platform and associated surgical instrumentation and accessories, perform as intended in a simulated clinical environment. This evaluation supports that system-level use, and minor material, dimensional and geometric differences, do not alter the ability to insert the ø5mm dilator into the disc space, maintain trajectory, or withstand forces associated with clinical use.	Results validate the functionality of the dilators and the compatibility with Medtronic Stealth™ Systems for navigated use. All acceptance criteria were met.

Test	Test Method Summary	Results/Conclusions
Porcine Study	The live porcine study was performed as supportive evidence to evaluate whether the modified neuromonitoring electrode surface area and new system interfaces and dilator material preserve the fundamental functional capability to produce measurable, orientation-dependent electromyographic (EMG) responses.	Results validate the directional neuromonitoring capabilities of the dilators. All acceptance criteria were met.
Electrical Safety	Electrical safety and performance testing per IEC 60601--1 verified acceptability of material, geometry, and electrode surface area changes.	All samples passed acceptance criteria.
Sterility, Sterile Packaging and Shelf Life	Assessments were performed to support the qualification of the Sterile Insulated Dilators for sterilization using established ethylene oxide (EO) cycles which have been validated to achieve a sterility assurance level of 10^{-6} in accordance with ISO 11135:2014. Packaging system integrity and sterile barrier performance were evaluated per ISO 11607-1 and ISO 11607-2. Subject dilators were evaluated against predicate Phantom XL Insulated Dilators to assess shelf-life.	All acceptance criteria for sterilization, packaging integrity, and shelf-life validation were met, confirming suitability of the device design and packaging configuration to maintain sterility, functionality, and material stability throughout the intended shelf-life and distribution conditions.
Biocompatibility	The Sterile Insulated Dilators were evaluated per ISO 10993-1 requirements for Externally communicating devices with tissue/bone for limited duration (≤24hr).	All testing passed acceptance criteria for specified materials, manufacturing, sterilization, and clinical use; biological risk assessment concluded that the dilators can be considered biocompatible for use as intended.
Usability Evaluation	Usability testing was justified as not required for conformity to IEC 62366-1; Considering clinical history of the predicate devices defined in review and intended use of the subject dilators, all risks after implementing mitigations were deemed acceptable. No new information was identified in the review of hazards and hazardous situations related to usability risk analysis.	
Navigation accuracy analysis	Medtronic performed proprietary evaluation to ensure that the navigation system is acceptable. The details of the testing as well as the associated report have been provided to FDA in MAF#3952. The results of this testing demonstrate that devices meeting the defined system compatibility requirements are capable of being used with the system as intended.	

Successful results for the aforementioned tests are included in this Traditional 510(k) submission. The non-clinical test results support a safety and effectiveness profile to establish substantial equivalence.

Design validation testing of the Sterile Insulated Dilator Kit was performed using human cadaver and porcine models with participation from practicing spine surgeons to ensure evaluation under clinically representative procedural conditions. The testing assessed device functionality, directional neuromonitoring performance, and its compatibility with the Medtronic Stealth™ Systems navigational system across all four dilator sizes (5 mm, 10 mm, 16 mm, and 20 mm).

The testing demonstrated that the dilators provided reliable sequential dilation and produced clear, directional neuromonitoring responses consistent with identifying nerve location and proximity during surgical access. The navigated 5 mm Insulated Dilator was successfully calibrated and tracked with Medtronic Stealth™ Systems to establish and confirm surgical position and trajectory relative to anatomical structures.

Biocompatibility endpoints for cytotoxicity, sensitization, irritation, acute systemic toxicity, and pyrogenicity were assessed according to the FDA Guidance within FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” for an Externally Communicating Device with contact with Tissue/Bone/ Dentin for a limited contact period (< 24 hours). A risk-based assessment was conducted to assess biocompatibility, and based on this the Medtronic Insulated Dilators were determined to be safe from a biocompatibility perspective.

All acceptance criteria were successfully met, confirming the device performs as intended and is suitable for its intended use. Overall, testing supports that the Sterile Insulated Dilators perform as intended for sequential dilation, directional neuromonitoring, and navigation-assisted access during spinal surgery.

F. Conclusion

Based upon the design, technology, performance, and intended use, the Sterile Insulated Dilators are substantially equivalent to the predicate device currently marketed under the Food, Drug and Cosmetic Act. The overall risk of the devices has been determined to be acceptable, confirming the Sterile Insulated Dilators are safe and effective.