October 29, 2026

Dixi Medical
% Golddy Kaur
President
Medtech Regulatory Strategist, Inc.
538, Daniel Clarke Way
Oakville, ON
Canada

Re: K260337
Trade/Device Name: SEEG-Tx® System (STX-SYS-001)
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency lesion probe
Regulatory Class: Class II
Product Code: GXI, GXD
Dated: January 23, 2026
Received: February 2, 2026

Dear Golddy Kaur:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JULIA E. SLOCOMB -S Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.10.29 16:07:38 -04'00'

for Ryan Trombetta, Ph.D.
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.	K260337

Please provide the device trade name(s).

SEEG-Tx® System (STX-SYS-001)

Please provide your Indications for Use below.

The SEEG-Tx® system is indicated for use in functional neurosurgical procedures to create radiofrequency lesions of brain tissue using MICRODEEP® depth electrodes.

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

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

SEEG-Tx® System – Traditional 510k

510(k) SUMMARY

This summary is prepared in accordance with the requirements of 21 CFR § 807.92

Date Prepared: Oct. 29, 2026

Submitter Information

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Regulatory Contact:

Ms. Golddy Kaur

Regulatory Affairs Consultant

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Subject Device:

Device Name (Trade/Proprietary Name): SEEG-Tx® System

Regulation Name: Radiofrequency Lesion Generator and Lesion Probe

Device Regulation Number: 21 CFR 882.4725

Product Codes: GXI, GXD

Device Classification: Class II

Predicate Device Identification:

Predicate Device Name: Cosman G4 RF Generator and Lesion Probe

Predicate Device Manufacturer: Boston Scientific

Primary Predicate Device:

Device Regulation Number: 21 CFR 882.4725

510(k): K050084

Product Code: GXI

Secondary Predicate Device:

Device Regulation Number: 21 CFR 882.4400

510(K): K082051

Product Code: GXD

Basis for Selection:

The predicate RF Generator was chosen as the predicate because it has the same intended use, namely, lesioning brain tissue for neurosurgical procedures, and similar technological characteristics as the subject device RF generator.

The predicate RF Lesion Probe was chosen as an additional predicate because it has the same intended use as the subject device, namely, to be connected to an RF Generator for lesioning nervous tissue for neurosurgical procedures, and similar technological characteristics as the subject device probe.

SEEG-Tx® System – Traditional 510k

Device Description

The SEEG-Tx® System is components consist of the:

- Radiofrequency (RF) lesion generator, Interface Box, and Interface cables.
- MICRODEEP® Depth Electrodes.

The SEEG-Tx® System uses radiofrequency energy to create lesions in an area of brain tissue that the neurosurgeon has identified for ablation. Qualified physicians utilize multiple modalities to localize the epileptogenic zone, and the implantation of MICRODEEP® depth electrodes is one such established method. Once the ablation sites are determined, the generator and accessories are taken to the patient's bedside and connected with the implanted electrodes, which then function as RF Probes for RF ablation.

The RF ablation is closed loop power-controlled with preset power output, rise time, and treatment duration to control the ablation process. The user selects the bipolar electrode sites and the contact configuration (2 or 3 adjacent contacts), then initiates the ablation process via the generator's touchscreen and controls. The generator continuously measures the tissue impedance to adjust the RF output current in order to maintain the target RF output power. The generator stops energy delivery should the impedance increase above its minimum value by a preset threshold, or when a preset duration is reached. The RF energy is transmitted through the SEEG-Tx® interface box to the user-defined contacts of the connected electrode via software-controlled switches.

Indications for Use

The SEEG-Tx® system is indicated for use in functional neurosurgical procedures to create radiofrequency lesions of brain tissue using MICRODEEP® depth electrodes.

Comparison of Subject Device to Predicate Device

Subject Device Classification Comparison - Generator			
	Subject Device SEEG-Tx® System	**Predicate Device** Cosman G4	**Equivalency Discussion**
510(k) Clearance	K260337	K082051	N/A
Device Name	SEEG-Tx® System	Cosman RF Generator	N/A
Classification	Class II	Class II	Same
Regulation Number	882.4400	882.4400	Same
Regulation Name	Radiofrequency Lesion Generator	Radiofrequency Lesion Generator	Same
Device Regulation Identification	A radiofrequency lesion generator is a device used to produce lesions in the nervous system or other tissue by the direct application of radiofrequency currents to selected sites.	A radiofrequency lesion generator is a device used to produce lesions in the nervous system or other tissue by the direct application of radiofrequency currents to selected sites.	Same
Product Code	GXD	GXD	Same

Subject Device Classification Comparison - Probe			
	Subject device DIXI MICRODEEP SEEG-Tx® Electrode	**Predicate device** Cosman RF Lesion Probe	**Equivalency Discussion**
510(k) Clearance	K260337	K050084	N/A
Device Name	SEEG-Tx® System	Cosman RF Lesion Probe	N/A
Classification	Class II	Class II	Same
Regulation Number	882.4725	882.4725	Same
Regulation Name	Radio Frequency Lesion Probe	Radio Frequency Lesion Probe	Same

Subject Device Classification Comparison - Probe			
	Subject device DIXI MICRODEEP SEEG-Tx® Electrode	**Predicate device** Cosman RF Lesion Probe	**Equivalency Discussion**
Device Regulation Identification	A radiofrequency lesion probe is a device connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired.	A radiofrequency lesion probe is a device connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired.	Same
Product Code	GXI	GXI	Same

Comparison of the Intended Use of the Subject Device to the Predicate

Intended Use Comparison – RF Generator and Probe			
	Subject Device **SEEG-Tx® System**	**Predicate Device** **Cosman G4**	**Equivalency Discussion**
Intended Use	The SEEG-Tx System consists of a generator and a SEEG electrode used for lesioning brain tissue for functional neurosurgical procedures.	RF Ablation System consists of a generator and probe used for lesioning nervous tissue for functional neurosurgical procedures.	Equivalent, as brain tissue is a subset of nervous tissue.
Indication for Use	The SEEG-Tx® system is indicated for use in functional neurosurgical procedures to create radiofrequency lesions of brain tissue using MICRODEEP® depth electrodes.	The Cosman G4 Radiofrequency Generator is indicated for use in procedures to create radiofrequency lesions for the treatment of pain, or for lesioning nerve tissue for	Removed reference to relief/treatment of pain and limited clinical anatomy for brain instead of nerve tissue. The subject device indications for use

		functional neurosurgical procedures. The Cosman G4 Radiofrequency Generator is used with separately approved (K050084) Cosman Radiofrequency Probes. RF Probe - Lesioning nerve tissue for functional neurosurgical procedures such as thalamotomies, pallidotomies, tractomies, and myelotomies; or procedures for pain relief.	does not separate the probe or the generator as they are defined as part of the SEEG-Tx® System.

Technological Performance Characteristics Comparison:

Comparison – RF Generator (K082051)			
	Subject Device **SEEG-Tx® System**	**Predicate Device** **Cosman G4**	**Equivalency Discussion**
Device Name	SEEG-Tx® Generator and SEEG-Interface Box	Cosman RF Generator	The SEEG-Interface Box connects RF power from the generator unit to the user-specified contacts of the SEEG-Tx® electrode.
Type of Control	For RF-TC: Rise time to fixed power level and hold for fixed duration, or until Δ impedance threshold is	For Continuous RF mode: Automatic and manual modes. In automatic mode the RF output voltage is automatically adjusted to target the Set Temp value.	Subject device applies power for lesioning without temperature feedback, as is done by the primary

SEEG-Tx® System – Traditional 510k

Comparison – RF Generator (K082051)			
	Subject Device **SEEG-Tx® System**	**Predicate Device** **Cosman G4**	**Equivalency Discussion**
	exceeded. (change from lowest impedance). Rise time and power levels are fixed based on the selection of bipolar 2 contacts or 3 contacts.	Once the Set Time interval has elapsed for, electrode output is disabled automatically. In manual mode generator will not control the Temperature at any electrode or check for Temperature-related errors. The RF output Voltage must be controlled manually by the user with the Output Control Knob.	predicate in manual mode. However, the primary predicate uses voltage control, not power control. The subject device equivalency has been established as demonstrated by our nonclinical performance testing.
Temperature Measurement	None	TCD electrode measures temperature via a thermocouple at the tip.	User can operate the predicate in manual mode where the temperature is displayed, but not used for control. The subject device does not measure or display temperature, instead using fixed parameters and power control to generate predictable lesions as demonstrated by the nonclinical performance testing.

SEEG-Tx® System – Traditional 510k

Comparison – RF Generator (K082051)			
	Subject Device **SEEG-Tx® System**	**Predicate Device** **Cosman G4**	**Equivalency Discussion**
Maximum Clinical Output Power (Software-Controlled)	- 2-contact bipolar configuration: 1.2 W - 3-contact bipolar configuration: 1.3 W	50 watts	The clinical output power of the subject device is substantially lower than the maximum output of the predicate device. The fixed preset parameters are software-controlled and non-adjustable by the user.
Power Delivery Modes	Continuous	Continuous and Pulsed	Subject device power delivery mode is equivalent to the continuous mode of the predicate device.
AC Power Compatibility	AC Line 100-240V	AC Line 100-240V	Same
Auto shutdown when the temperature exceeds safe levels	No temperature feedback. However, the device has an auto shutdown when the impedance increases from its minimum by a set threshold.	Yes	Subject device applies power for lesioning without temperature feedback, as is done by the primary predicate in manual mode. However, the primary predicate uses voltage control, not power control.

SEEG-Tx® System – Traditional 510k

Comparison – RF Generator (K082051)			
	Subject Device **SEEG-Tx® System**	**Predicate Device** **Cosman G4**	**Equivalency Discussion**
			The subject device equivalency has been established as demonstrated by our nonclinical performance testing.
Electrical and EMC Safety	IEC 60601-1 and IEC 60601-1-2 compliant	IEC 60601-1 and IEC 60601-1-2 compliant	Same
RF Energy Delivery Mode	Power Control: The power is ramped until the set power is reached. The power is maintained at this level until the set duration is reached. Impedance is monitored continuously and is used to adjust the output current to maintain the set power.	Temperature Control: Voltage is ramped steadily until the set temperature is reached, then the voltage is adjusted to maintain the set temperature.	Power control keeps the power constant. As the impedance increases due to progressive desiccation of the tissue, the current is reduced to keep the delivered power constant, thereby preventing runaway heating. The subject device equivalency has been established as demonstrated by our nonclinical performance testing.

SEEG-Tx® System – Traditional 510k

Comparison – RF Generator (K082051)			
	Subject Device **SEEG-Tx® System**	**Predicate Device** **Cosman G4**	**Equivalency Discussion**
RF Energy Channels	Bipolar 2- contact and Bipolar 3-contact (middle vs. outer contacts)	Monopolar Bipolar	Subject device does not have a monopolar mode of action. Predicate device does not have a 3-contact probe.
Impedance Measurement	50 Ω - 2 k Ω	0 - 3 KΩ	Subject device - Output disabled on open circuit or short circuit (< 50 Ω) detection.
User Interface	Touchscreen	Touchscreen	Same
USB port for servicing	Yes	Yes	Same
RF Output Waveform	Sine wave	Sine wave	Same
RF Output Voltage	max 65 Vrms	0 to 70 volts RMS into 100Ω load during Thermal RF output.	Within the maximum voltage of the reference predicate. Power is controlled, therefore voltage applied is a function of impedance. Safety is demonstrated by our nonclinical performance testing.
RF Output Current	max 200 mA	0 to 700 mA RMS	Less than the primary predicate

SEEG-Tx® System – Traditional 510k

Comparison – RF Generator (K082051)			
	Subject Device **SEEG-Tx® System**	**Predicate Device** **Cosman G4**	**Equivalency Discussion**
RF Output Power	Maximum 10W	0 to 50 watts RMS (into 100Ω load)	Less than the primary predicate.
RF Frequency	488 kHz	480 kHz	Equivalent
RF Impedance Range	150 – 2000 Ω	0 – 3000 Ω	The impedance range is similar to the range of the predicate.
Display Parameters	Power (value and trend graph) Impedance (value and trend graph) Current (value) Voltage (value) Application time (sec)	Values for: Voltage (V) Temperature (degree c) Impedance (Ohms) Current (mA) Power (W) Application time (sec)	Temperature is not displayed. The use of impedance as control feedback is demonstrated by our nonclinical performance testing.
Accessories	None	None	Same

Predicate Comparison – RF Lesion Probe (K050084)			
	Subject Device **SEEG-Tx® System**	**Predicate Device** **Cosman Lesion Probe**	**Equivalency Discussion**
Device Name	SEEG-Tx® MICRODEEP Electrode	Cosman RF Probe	N/A
RF Probe Configuration	Single closed lumen	Single closed lumen	Same

Predicate Comparison – RF Lesion Probe (K050084)			
	Subject Device **SEEG-Tx® System**	**Predicate Device** **Cosman Lesion Probe**	**Equivalency Discussion**
Temperature Measurement Capabilities	No	Yes	Ablation parameters are powered controlled, and voltage applied is a function of impedance. Safety is demonstrated by nonclinical performance data.
Patient Contact Materials	Platinum – contact	Stainless steel	Equivalent as both materials are biocompatible
Compatibility with RF Generator	With SEEG-Tx® Generator connected via SEEG-Tx® Interface Box	With the Cosman Generator using compatible adapters	Equivalent
Electrode Active Length	5 to 18 contacts per electrode with 2 mm contact size. Contact spacing varies, but is not less than 1.5 mm.	2 mm, 4 mm or 10 mm	Contact size is the same as the smallest predicate probe
Diameter	0.8mm	1.1 mm or 1.6 mm	The subject device has a smaller diameter.
Number of contacts	4-18 contacts per electrode	1 contact per probe	Subject device has more contacts. User selects the adjacent 2 or 3 contacts to use for each ablation site.
Nervous tissue lesioning	Yes, limited to brain lesions	Yes	Equivalent, as brain tissue is a subset of nervous tissue.

System Characteristics:

User: Neurosurgeons familiar with RF lesion techniques

Anatomical Site of Use - Brain tissue

Access Method - Transcranial

Energy Type - Radiofrequency

Procedure Type - Ablation

Principle of Operation - Automated RF delivered from RF generator to the SEEG-Tx Microdeep Electrode to create lesions in brain tissue

Mechanism of Action - Cellular necrosis through thermal coagulation

System Feedback Mechanism – Power controlled

Ability to Make Multiple Lesions – Yes

Summary of Performance Testing

The following performance data were provided in support of the substantial equivalence determination for the SEEG-Tx® System. Performance testing of the system was conducted to demonstrate compliance with its performance specifications. The results of design verification and validation activities did not raise any new or different safety or effectiveness questions. The risk management process was used throughout the Design & Development, Verification, and Validation activities in accordance with ISO 14971.

A summary of the non-clinical testing is presented in the table below:

Nonclinical Performance Tests		
Tests	**Overview Summary**	**Results**
Ablation Profile	Verification of Power, Current, Voltage, and Δ impedance output accuracy during thermocoagulation in the 2-contact and 3-contact configurations.	Pass

Nonclinical Performance Tests		
Tests	**Overview Summary**	**Results**
Thermal profile	An ex vivo porcine brain model was used to assess continuous time temperature thermal profiles. The energy hold and decay are stable. The temperature measurements are replicable and within the performance envelope of the predicate. A histopathological study used an ex vivo porcine brain model to measure the extent of damage (Thermally Adversely Affected Regions, TAAR) using co-registered H&E and TTC gross viability stains. TAAR dimensions for subject device configurations fell within the envelope bounded by the low-power and high-power predicate settings across both staining methods.	Substantially equivalent to the predicate
Mechanical Performance	Verification of the system's mechanical and electrical connections compliance as described in the test protocols.	Pass
System Performance	Measurement of ramp time, output power, output power accuracy, and duration during the standard ablation procedure (in Bipolar 2-contacts and Bipolar 3-contacts) (As described in test protocols).	Pass

SEEG-Tx® System – Traditional 510k

Nonclinical Performance Tests		
Tests	**Overview Summary**	**Results**
Generator System	The tests were performed to verify the generator hardware and software specifications.	Pass
Electromagnetic and Electrical Safety	Test methods prescribed by IEC 60601-1-2:2014+A1:2020 Test methods prescribed by IEC 60601-1:2005/AMD:2012/AMD2:2020	Pass
Packaging Integrity	Verified to meet applicable standards to ensure the product withstands the conditions of packaging, shelf life, and distribution testing.	Pass
Sterilization	The sterilization process is validated to demonstrate a minimum of SAL of 10-6 for the product.	Pass Ref. K170959
Software	Software is developed and verified as per recognized standards and guidance. (FDA Guidance “Content of Premarket Submissions for Software Contained in Medical Devices “issued on: May 11, 2005 and applicable requirements of IEC 62304).	Pass
Cybersecurity	Cybersecurity analysis was performed in accordance with “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” – Final Guidance October 2, 2014, and “Cybersecurity in Medical Devices: Quality System Considerations.	Pass

Nonclinical Performance Tests		
Tests	**Overview Summary**	**Results**
Biocompatibility	Patient contacting parts are tested in accordance with the Biocompatibility Standards.	Passed Ref. K170959
Usability Validation	Usability was validated primarily by having representative users carry out simulated patient treatments on the SEEG-Tx System. This was supplemented by knowledge and interview questionnaires of the same users. The methods used for validation are described in the Usability Validation Protocol.	Pass

Conclusions

The subject device and predicate devices have the same Intended Use, Device Regulation Number/Name/Identification and Product Codes. The differences in the Indications for Use and Fundamental Scientific Technology between the subject device, and the predicate do not raise new questions regarding safety and effectiveness when compared. Conclusions drawn from the nonclinical testing demonstrate the device is as safe, as effective, and performs as well as the legally marketed device predicates, per 21 CFR 807.92(b)(3). The SEEG-Tx® System is substantially equivalent to the predicate devices.