March 28, 2025

Turing Medical Technologies, Inc.
Christa Nova
Director of Quality Assurance and Regulatory Affairs
393 N Euclid Ave
Suite 310
Saint Louis, Missouri 63108

Re: K243520
Trade/Device Name: Bullsai Confirm
Regulation Number: 21 CFR 882.5855
Regulation Name: Brain Stimulation Programming Planning Software
Regulatory Class: Class II
Product Code: QQC
Dated: March 14, 2025
Received: November 15, 2024

Dear Christa Nova:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Jitendra V. Virani -S

CDR Jitendra Virani
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243520

Device Name

Bullsai Confirm

Indications for Use *(Describe)*

Bullsai Confirm provides functionality to assist medical professionals in planning the programming of stimulation for patients receiving approved Abbott deep brain stimulation (DBS) devices.

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.

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"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

Device Trade Name:	Bullsai Confirm
Manufacturer:	Turing Medical Technologies, Inc. 393 N EUCLID AVE STE 310, SAINT LOUIS, MISSOURI 63108 UNITED STATES
Contact:	Christa Nova Director, QARA 419-388-3288
Date Prepared:	March 28, 2025
Classification:	Brain stimulation programming planning software, 21 CFR 882.5855
Class:	II
Product Code:	QQC
Primary Predicate:	SureTune4 Software, DEN210003

Indications For Use:
Bullsai Confirm provides functionality to assist medical professionals in planning the programming of stimulation for patients receiving approved Abbott deep brain stimulation (DBS) devices.

Device Description:
Bullsai Confirm is intended to assist medical professionals in planning the programming of deep brain stimulation (DBS) by visualizing the Volume of Tissue Activated (VTA) relative to patient anatomy. It is used to visualize patient-specific information within the patient's anatomy. Integrated magnetic resonance imaging (MRI) and computed tomography (CT) images are uploaded to Bullsai Confirm and can be navigated through in multiple 2D projections and 3D reconstructions. Abbott DBS lead models are positioned in the corresponding artifacts and potential stimulation settings and electrode configurations entered. Bullsai Confirm mathematically combines finite element (FE) based electric field model of the lead with an axon based neural activation model to translate potential stimulation settings and electrode configurations into a visualized VTA field to indicate the shape and the area or volume of anatomy that will be activated by the stimulation. Results, including input image quality assessments, are shared in an output PDF report and visualized in a web-based software interface.

Bullsai Confirm is used to do the following:

- Import DICOM images from a picture archiving and communication system (PACS), including MRI and CT DICOM images.
- Import preoperative planning outputs (including tractography, structural ROIs, etc.) from AWS S3 Cloud Storage
- Combine MR images, CT images, and patient specific 3D structures for more detail
- Localize graphical compatible DBS lead models (based on preoperative imaging)
- Visualize VTA fields relative to structures of interest in the patient anatomy or lead position

The software provides a workflow for clinicians to:

- Create patient-specific stimulation plans for DBS programming
- Export reports that summarize stimulation plans for patients (PNG screenshot)

Predicate Device:

Turing Medical Technologies, Inc. submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, Bullsai Confirm is substantially equivalent in indications, design principles, and performance to the following predicate device.

Primary Predicate: SureTune4 Software (DEN210003)

Substantial Equivalence:

Item	Predicate: SureTune4 Software DEN210003	Subject Device: Bullsai Confirm	Comparison
Classification	Class II	Class II	Identical
Product Code	QQC	QQC	Identical
Device Description	The SureTune4 Software is intended to assist medical professionals in planning the programming of deep brain stimulation (DBS) by visualizing the Volume of Neural Activation (VNA) relative to patient anatomy. It is used to visualize patient-specific information within the patient's anatomy. Integrated preoperative and postoperative magnetic resonance imaging (MRI), O-armTM, and computed tomography (CT) images are uploaded to SureTune4 and can be navigated through in multiple 2D projections and 3D reconstructions. Medtronic DBS lead models are positioned in the corresponding artifacts and potential stimulation settings and electrode configurations entered. The SureTune4 Software mathematically combines finite element (FE) based electric field model of the lead with an axon based neural activation model to	Bullsai Confirm is intended to assist medical professionals in planning the programming of deep brain stimulation (DBS) by visualizing the Volume of Tissue Activated (VTA) relative to patient anatomy. It is used to visualize patient-specific information within the patient's anatomy. Integrated magnetic resonance imaging (MRI) and computed tomography (CT) images are uploaded to Bullsai Confirm and can be navigated through in multiple 2D projections and 3D reconstructions. Abbott DBS lead models are positioned in the corresponding artifacts and potential stimulation settings and electrode configurations entered. Bullsai Confirm mathematically combines finite element (FE) based electric field model of the lead with an axon based neural activation model to translate potential stimulation settings and electrode configurations	Similar; 1) Bullsai Confirm does not import or combine O-arm™ images. 2) Bullsai Confirm does not import from physical media. 3) Bullsai Confirm shares results, including input image quality assessments, in an output PDF report and visualized in a web-based software interface. 4) Bullsai Confirm does not enter electrophysiological annotations. 5) Bullsai Confirm does not superimpose an anatomical atlas. 6) Bullsai Confirm does not manually segment structures of

	translates potential stimulation settings and electrode configurations into a visualized VNA field to indicate the shape and the area or volume of anatomy that will be activated by the stimulation. The SureTune4 software is used to do the following: • Import MR, O-arm™, and CT patient images over a DICOM network or from physical media (hard drive, USB drive, CD, or DVD) • Import DICOM archives from StealthStation™ S7TM systems with Cranial 3.x software and StealthStation™ S8 Cranial software systems, and SureTune4 systems over a DICOM network • Combine MR, O-arm™ and CT images for more detail • Superimpose an anatomical atlas to better understand the position of structures of interest relative to a patient's anatomy • Manually segment structures of interest to highlight particular brain structures • Localize graphical Medtronic DBS lead models (based on preoperative imaging) • Enter electrophysiological annotations • Visualize VNA fields relative to structures of interest in the patient anatomy or lead position • Create patient-specific stimulation plans for DBS programming • Generate reports that summarize stimulation plans for patients • Export patient sessions to SureTune4 XLS spreadsheets (in Microsoft™ Excel format)	into a visualized VTA field to indicate the shape and the area or volume of anatomy that will be activated by the stimulation. Results, including input image quality assessments, are shared in an output PDF report and visualized in a web-based software interface. Bullsai Confirm is used to do the following: • Import DICOM images from a picture archiving and communication system (PACS), including MRI and CT DICOM images. • Import preoperative planning outputs (including tractography, structural ROIs, etc.) from AWS S3 Cloud Storage • Combine MR images, CT images, and patient specific 3D structures for more detail • Localize graphical compatible DBS lead models (based on preoperative imaging) • Visualize VTA fields relative to structures of interest in the patient anatomy or lead position The software provides a workflow for clinicians to: • Create patient-specific stimulation plans for DBS programming • Export reports that summarize stimulation plans for patients (PNG screenshot)	interest to highlight particular brain structures.

Indication for Use	The SureTune4 Software is indicated to assist medical professionals in planning the programming of stimulation for patients receiving approved Medtronic deep brain stimulation (DBS) devices.	Bullsai Confirm provides functionality to assist medical professionals in planning the programming of stimulation for patients receiving approved Abbott deep brain stimulation (DBS) devices.	Similar

Bullsai Confirm is substantially equivalent to the identified predicate (legally marketed) device. Bullsai Confirm has the same intended use and technological characteristics as the predicate device and or different intended use and technological characteristics that do not raise different questions of safety and effectiveness.

At a high level, Bullsai and predicate device are based on the following same elements:

- Bullsai Confirm is intended to assist medical professionals in planning the programming of deep brain stimulation (DBS).
- Bullsai Confirm visualizes neural activation tissue through Volume of Tissue Activated (VTA).
- Bullsai Confirm visualizes relative to patient anatomy.
- Bullsai Confirm is used to visualize patient-specific information within the patient's anatomy.
- Bullsai Confirm imports preoperative and postoperative MR and CT images.
- Bullsai Confirm displays integrated preoperative and postoperative MR and CT images.
- Bullsai Confirm accepts uploaded images which can be navigated through in multiple 2D projections and 3D reconstructions.
- Bullsai Confirm positions DBS lead models in the corresponding artifacts, and potential stimulation settings and electrode configurations are displayed.
- Bullsai Confirm mathematically combines finite element (FE) based electric field model of the lead with an axon based neural activation model to translates potential stimulation settings and electrode configurations into a visualized field to indicate the shape and the area or volume of anatomy that will be activated by the stimulation.
- Bullsai Confirm imports patient images.
- Bullsai Confirm uses DICOM networks (PACS).
- Bullsai Confirm uses DBS lead models.
- Bullsai Confirm combines images for more detail.
- Bullsai Confirm localizes graphical DBS lead models based on preoperative imaging.
- Bullsai Confirm visualizes fields relative to structures of interest in the patient anatomy or lead position.
- Bullsai Confirm provides a workflow for clinicians to create and export patient-specific summary stimulation plans.

At a high level, Bullsai Confirm and predicate device have the following different elements:

- Bullsai Confirm does not import or combine O-arm™ images.
- Bullsai Confirm does not import from physical media.
- Bullsai Confirm shares results, including input image quality assessments, in an output PDF report and visualized in a web-based software interface.
- Bullsai Confirm does not enter electrophysiological annotations.
- Bullsai Confirm does not superimpose an anatomical atlas.
- Bullsai Confirm does not manually segment structures of interest to highlight particular brain structures.

Performance Data:
The subject device meets the special controls under 21 CFR 882.5855 for brain stimulation programming planning software, which include the following:

1. Software verification, validation, and hazard analysis must be performed.
2. Usability assessment must demonstrate that the intended user(s) can safely and correctly use the device.
3. Labeling must include:
    a. The implanted brain stimulators for which the device is compatible.
    b. Instructions for use.
    c. Instructions and explanations of all user-interface components.
    d. A warning regarding use of the data with respect to not replacing clinical judgement.

A hazard analysis and software verification and validation testing were performed for Bullsai Confirm. Bullsai Confirm also underwent formative usability testing and technical performance evaluation of the lead artifact detection and registration between image types. The User Manual for Bullsai Confirm contains the labeling statements in accordance with the special controls.

Conclusion:
The subject device and the predicate devices have the same intended use and have similar technological characteristics. The data included in this submission demonstrates substantial equivalence to the predicate device listed above.