DE NOVO CLASSIFICATION REQUEST FOR SURETUNE4 SOFTWARE

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Brain stimulation programming planning software. The brain stimulation programming planning software is a prescription device intended to assist in planning stimulation programming for implanted brain stimulators.

NEW REGULATION NUMBER: 21 CFR 882.5855

CLASSIFICATION: Class II

PRODUCT CODE: QQC1

BACKGROUND

DEVICE NAME: SureTune4 Software

SUBMISSION NUMBER: DEN210003

DATE OF DE NOVO: February 3, 2021

SPONSOR INFORMATION: Medtronic Neuromodulation
7000 Central Ave., N.E.
Minneapolis, Minnesota 55432

INDICATIONS 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.

LIMITATIONS

The sale, distribution, and use of the SureTune4 are restricted to prescription use in accordance with 21 CFR 801.109.

SureTune4 Software does not replace clinical judgment.

Warning: All DBS programming decisions remain in the programming clinician's judgment. All programmed settings should be screened and selected based on patient physiological response. Reliance on anatomy data in place of clinical judgment could result in excessive stimulation, inadequate stimulation, or stimulation to an unintended

target.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

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-arm™, 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 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™ S7™ 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)

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this De Novo request, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

SUMMARY OF NONCLINICAL/BENCH STUDIES

SOFTWARE

The submission contained all of the elements of software documentation corresponding to the "Moderate" level of concern, as outlined in the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Adequate documentation describing the software/firmware, software specifications, architecture design, software development environment, traceability, revision level history, unresolved anomalies provide the foundation that the software will operate in a manner as described in the specifications. Hazard analysis was performed to characterize software risks including device malfunction and measurement related errors. The submission included verification and validation (V&V) testing to address the potential hazards with satisfactory results.

Software design verification was done to establish objective evidence to ensure design outputs have met design input requirements. The following testing was performed, and all testing met the acceptance criteria as defined in the verification protocols, successfully providing objective evidence that the final design was verified to meet the design input requirements.

- Patient image import from PACS or physical media
- SureTune data archive import and export
- StealthStation archive import
- Patient and session management
- Patient image viewing
- AC/PC definition and visualization
- Patient image fusion (registration)
- Import of read-only stereotaxic frame registration for supported frames
- Anatomical atlas segmentation and visualization
- Anatomical manual segmentation and visualization
- Planned surgical lead trajectory definition and visualization
- Automatic and manual positioning/orientation of non-directional and directional DBS leads
- Electrophysiological input and visualization
- Volume of neural activation generation and visualization
- Planned stimulation settings report output
- Patient fiber tract visualization
- Receive and send DICOM data over the network using DICOM protocols
- Clinician Programmer network data transfer
- Client/Server network data transfer
- SureTune Server configuration
- SureTune Software Installation

SUMMARY OF CLINICAL INFORMATION

Clinical performance testing was not provided for the SureTune4. Instead, the sponsor performed a user needs validation study and a formative usability evaluation.

User Needs Validation Study
Purpose: To determine whether the device meets user needs
Subjects: 8 (5 Neurologist (N)/3 Neurosurgeons (NS))
Prior to testing, participants received training on the SureTune4 software features and functions.
Testing consisted of the following two main categories of questions:

- Q1: Meet need to visualize anatomy & simulated stimulation field?
- Q2: Meet need to segment anatomy from patient images?

The participants were asked to rate the user needs on a scale of 1-5. An average score of 3 or higher for the user needs was considered a pass.

Results: All user needs received an average rating of 3 or greater; therefore, the protocol passed.

Formative Usability Evaluation
Purpose: To identify use difficulties and assess safety and efficacy of use
Subjects: 15 (8 NS/7 N)
Consisted of Simulated Use Testing with the following use scenarios:

- Task Completion
- Trends in Use Difficulties
- Qualitative Feedback
- Participant Safety Scores

Results: Passed – Some minor use difficulties were observed but were appropriately mitigated.

Pediatric Extrapolation
In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The labeling is sufficient and satisfies the requirements of 21 CFR 801.109 for prescription devices. In addition to adequate instructions for use, the labeling must include the following regarding the limitations of the device:

- The implanted brain stimulators for which the device is compatible.

- Warning: SureTune4 Software does not replace clinical judgment. All DBS programming decisions remain in the programming clinician's judgment. All programmed settings should be screened and selected based on patient physiological response. Reliance on anatomy data in place of clinical judgment could result in excessive stimulation, inadequate stimulation, or stimulation to an unintended target

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of brain stimulation programming planning software.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	Mitigation Measures
Suboptimal stimulation settings leading to temporary injury or impairment and/or ineffective stimulation	Software verification, validation, and hazard analysis Usability assessment Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the brain stimulation programming planning software is subject to the following special controls:

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.

BENEFIT/RISK DETERMINATION

The risks of the device are based on software verification, validation, and hazard analyses, as well as data collected in human factors and usability clinical studies described above. The risks of the device include temporary injury or impairment and/or ineffective stimulation due to suboptimal stimulation settings and/or software failure. These are mitigated by the following:

- The SureTune4 has no direct link with the implanted device and its programming,
- Usability assessment,
- Labeling states that all programming decisions remain in the programming clinician's judgment and programmed settings should be screened and selected based on patient physiological response.
- Labeling states that the VNA models a visual representation of neuronal tissue activation across a range of stimulation settings and electrode configurations and does not replace observation of the patient for therapeutic effects or side effects.
- Software documentation including verification and validation testing and hazard analysis.

The probable benefits of the device are based on nonclinical laboratory studies as well as data collected in human factors and usability clinical studies as described above. In support of the De Novo, the sponsor has provided software documentation and verification and validation testing,

VNA modeling description and justification, human factors/usability testing, auto-detect lead orientation algorithm accuracy testing, image fusion accuracy testing, and cybersecurity information and testing. All testing passed prespecified acceptance criteria and no safety concerns were raised.

Additional factors to be considered in determining probable risks and benefits for the SureTune4 include the following sources of uncertainty associated with the device: accuracy of the VNA model, accuracy of the anatomy segmentation, and no data to demonstrate it can optimize programming. However, no claims are associated with these aspects of the device and as a tool, the testing provided evidence of a clinical benefit for this device.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

> 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.

The probable benefits outweigh the probable risks for the SureTune4 Software. The device provides benefits and the risks can be mitigated by the use of general and the identified special controls.

CONCLUSION

The De Novo request for the SureTune4 Software is granted and the device is classified under the following:

> Product Code: QQC
> Device Type: Brain stimulation programming planning software
> Class: II
> Regulation: 21 CFR 882.5855