# SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

## I. GENERAL INFORMATION

Device Generic Name: Stimulator, Electrical, Implanted, for the treatment of tremor

Device Trade Name: Vercise PC Deep Brain Stimulation (DBS) System
Vercise Gevia Deep Brain Stimulation (DBS) System
Vercise Genus Deep Brain Stimulation (DBS) System

Device Procodes: NHL, PJS, and MHY

Applicant's Name and Address: Boston Scientific Corporation
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Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P150031/S064

Date of FDA Notice of Approval: TBD

The Vercise PC Deep Brain Stimulation (DBS) System and the Vercise Gevia Deep Brain Stimulation (DBS) System were originally approved on January 10, 2019 under P150031/S001. The Vercise Genus DBS System was approved on January 21, 2021 under P150031/S034. These systems are indicated for use in the following:

- Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa-responsive Parkinson's disease (PD) that are not adequately controlled with medication.

- Bilateral stimulation of the internal globus pallidus (GPi) as an adjunctive therapy in reducing some of the symptoms of advanced levodopa responsive Parkinson's disease (PD) that are not adequately controlled with medication.

- Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

The current supplement (P150031/S064) was submitted to expand the indication for the Vercise PC, Vercise Gevia, and Vercise Genus DBS Systems. The original PMA (P150031) for the Vercise DBS System was approved on December 8, 2017 and the SSED to support the indication for STN stimulation is available on the CDRH website (https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150031B.pdf) and is incorporated by

reference here. No new clinical data were required to support the approval of the Vercise PC, Vercise Gevia and Vercise Genus Deep Brain Stimulation (DBS) Systems.

## II. INDICATIONS FOR USE

The Vercise PC, Vercise Gevia and Vercise Genus DBS systems were previously indicated for use in the following:

- Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa-responsive Parkinson's disease (PD) that are not adequately controlled with medication.

- Bilateral stimulation of the internal globus pallidus (GPi) as an adjunctive therapy in reducing some of the symptoms of advanced levodopa responsive Parkinson's disease (PD) that are not adequately controlled with medication.

- Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

In this SSED, the current supplement was submitted to expand the indication for the Vercise PC, Vercise Gevia and Vercise Genus DBS systems to include:

- Bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of disabling upper extremity tremor in adult essential tremor patients whose tremor is not adequately controlled by medications and where the tremor constitutes a significant functional disability.

## III. CONTRAINDICATIONS

The Boston Scientific Vercise PC, Vercise Gevia and Vercise Genus DBS Systems or any of its components, are contraindicated for:

- **Diathermy:** Shortwave, microwave, and/or therapeutic ultrasound diathermy should not be used on patients implanted with the Boston Scientific DBS System, or any of the system components. The energy generated by the diathermy can be transferred to the Boston Scientific DBS System, causing tissue damage in the brain resulting in severe injury or death.
- **Electroconvulsive therapy (ECT) and transcranial magnetic stimulation (TMS)** The safety of these therapies in patients implanted with the DBS System has not been established. It is possible that the energy generated by these therapies can be transferred to the DBS System, causing tissue damage that may result in severe patient injury or death.

- **Magnetic Resonance Imaging (MRI).** Patients implanted with the Vercise PC DBS System (DBS Leads, Lead Extensions and Stimulator) should not be subjected to an

MRI. MRI exposure may result in the following:

- Dislodgement of implanted components
- Heating of the Contacts, or other system components, causing permanent tissue lesioning
- Damage to the Stimulator's electronics
- Current induction through the DBS Leads and Vercise PC DBS System causing unpredictable levels of stimulation
- Distortion of the diagnostic image
- Personal injury or death

**Note:** The Lead-only system (before Stimulator is implanted), the Vercise Gevia System, and the Vercise Genus System are MR Conditional. An MRI examination can be conducted safely when all the instructions in the supplemental manual ImageReady™ MRI Guidelines for Boston Scientific DBS Systems are followed. MR Conditional labeling for the DBS standard Leads (Models DB-2201-30-AC, DB-2201-30-DC, DB-2201-45-BC, DB-2201-45-DC) and DBS Directional Leads (Models DB-2202-30 and DB-2202-45) was approved in PMA Supplements P150031/S5 and P150031/S11. MR Conditional labeling for the Vercise Gevia System and the Vercise Genus System was approved in P150031/S011 and P150031/S034 respectively. For the latest version of the manual go to www.bostonscientific.com/manuals.

- **Patient Incapability.** Patients who are unable to properly operate the Remote Control and Charging System (when applicable) should not be implanted with the Boston Scientific DBS Systems.
- **Poor Surgical Candidates.** The Boston Scientific DBS Systems are not recommended for patients who are poor surgical candidates.
- **Unsuccessful Test Stimulation.** The Boston Scientific DBS Systems should not be used in patients who experience unsuccessful test stimulation.

## IV. WARNINGS AND PRECAUTIONS

The warnings and precautions are provided in the Vercise PC, Vercise Gevia, and Vercise Genus DBS System labeling.

## V. DEVICE DESCRIPTION

The Vercise PC, Vercise Gevia and Vercise Genus DBS Systems (Figure 1) include non-rechargeable and rechargeable Stimulators, with DBS Leads for stimulation of selected targets (i.e., the subthalamic nucleus, globus pallidus internus and ventral intermediate nucleus of the thalamus) in the brain. DBS Extensions are used to connect the DBS Leads to the Stimulator implanted near the clavicle, as seen in Figure 2.

The DBS Systems utilize current steering across eight contacts per DBS Lead, which is intended to provide precise positioning of stimulation. The Stimulator is controlled by a

handheld Remote Control, and can be programmed by a Clinician Programmer using the Vercise Neural Navigator Software. Periodically, the rechargeable Stimulator battery must be replenished with a radiofrequency (RF) charging device provided in the Charging Kit.

**Figure 1. Vercise PC, Vercise Gevia and Vercise Genus DBS Systems**

**Figure 2. Typical Implant Location**

## A. Implanted Components

- Implantable Pulse Generator (IPG, Model # DB-1140-S, DB-1200-S, DB-1216, DB-1232, DB-1408, DB-1416, DB-1432): 8, 16 and 32-contact, multi- channel, implantable pulse generators. The Vercise PC IPG Model# DB- 1140-S and the Vercise Genus IPG Model #s DB-1408, DB-1416 and DB-1432 have a non-rechargeable power source. The Vercise Gevia IPG Model# DB-1200-S and the Vercise Genus IPG Model #s DB-1216, DB-1232 have a rechargeable power source. The IPGs generate programmable electrical pulses that are conducted to targets in the brain via leads. The IPGs can support up to two 8-contact Leads. A charge density warning appears on the Clinician Programmer when stimulation settings are set to deliver $\geq 30\mu C/cm^2$/phase. All contacts have independent current control. Table 1 below provides a summary of the programmable stimulation parameters.

**Table 1: Vercise PC, Vercise Gevia and Vercise Genus DBS System Stimulation Parameters**

| Parameters | Range |
|---|---|
| Waveform | Charge balanced asymmetric biphasic |
| Pulse Shape | Rectangular |
| Current or Voltage Regulated | Current |
| Amplitude Range | 0 - 12.7 mA per contact (up to 20.0 mA per Area) |
| Pulse Width Range | 20µs - 450µs |
| Frequency Range[1] | 2 - 255Hz |
| Contact Connections (i.e., Channels) | 8, 16 or 32 |
| Independent Areas of Stimulation (4 Programs with 4 Areas per Program) | 16 |
| Current Path Options | Unipolar, Bipolar, or Multipolar |

[1]The rate is limited to 255 Hz for a given area. The global rate limit for each Lead is also 255 Hz.

- Leads (Model # DB-2201-xx, DB-2202-xx, xx = 30 or 45, i.e., length of 30cm or 45cm): The DBS leads deliver electrical pulses generated by the IPG to targets in the brain. The DBS Lead model DB-2201 has 8 cylindrical ring contacts at the distal end. The DBS Lead model DB-2202 has 2 ring contacts and two rows of directional contacts that are segmented circumferentially to allow both axial and rotational stimulation selectivity. Each segmented contact covers 90 degrees of the Lead circumference. The lead specifications are provided in Table 2 below.

**Table 2: DBS Lead Specifications**

| Feature | Description | |
|---|---|---|
| | DB-2201 Lead | DB-2202 Lead |
| Number of Contacts | 8 | 8 |
| Contact Length | 1.5 mm | 1.5 mm |
| Ring Contact Surface Area | 6.0 $mm^2$ | 6.0 $mm^2$ |
| Segmented Contact Surface Area | N/A | 1.5 $mm^2$ |
| Contact Spacing (axial) | 0.5 mm | 0.5 mm |
| Contact Span | 15.5 mm | 7.5 mm |
| Distal Contact to Tip Length | <1.3 mm | N/A |
| Diameter | 1.3 mm | |
| Overall Length | 30 cm, 45 cm | |
| Outer Jacket Tubing (Insulation) | Polyurethane | |
| Contact Material | Platinum/Iridium | |
| Impedance (Ω) | ≤ 90 (measured from each connector to corresponding electrode contact) | |

- Lead Extension (Model # NM-3138-55 and DB-3128-xxB, xx = 55 or 95, i.e., length of 55 cm or 95 cm): The DBS Extension consists of a single or dual 8-port connector at the distal end and a single or dual tails with 8 cylindrical contacts each at the proximal end. The DBS Lead may be inserted and secured into the connector, that align with the contacts on the DBS Lead to form electrical connections. The proximal end is inserted into the IPG.

- Implantable Accessories:
  - Burr Hole Cover: The Burr Hole Cover is used to permanently secure the DBS lead and to cover the burr hole created in the skull during the surgical implantation of the DBS lead.
  - DBS Lead Boot: The DBS Lead Boot protects the proximal end of the DBS Lead prior to the Stimulator implant surgery.
  - Suture Sleeve: The Suture Sleeve may be used to anchor the DBS Lead or DBS Extension to the fascia.
  - Implantable Adapters: The M8 and S8 Adaptors connect Medtronic and Abbott Leads to the Boston Scientific IPG.

**B. <u>External Components</u>**

- ETS (Model # DB-5132-S, DB-5170): The External Trial Stimulator (ETS) is a component that may be used for intraoperative testing of stimulation. It provides the identical stimulation capabilities as the IPG.

- Remote Control (Model # DB-5250-S, DB-5270): The Remote Control is a hand-held, battery operated unit that uses telemetry to communicate with the IPG and ETS. It allows the patient to control the stimulation therapy prescribed by the clinician (e.g., turn DBS system on and off).
- Charger (Model # NM-5312): The Charger uses radiofrequency (RF) energy to inductively charge the implanted IPG battery when the Charger is placed externally over the IPG implant site.

- Base Station (Model # NM-5305): The Base Station connects to a wall-mounted power supply and is utilized to recharge the Charger.

- Clinician Programmer (Model # DB-7161, NM-7161, DB-7161R, NM-7161R, DB-7164, NM-7164, DB-7164R, NM-7164R): The Clinician Programmer is used by the clinician to program the IPG and ETS, and thus prescribe stimulation therapy for the patient.

- Non-implantable or External Accessories:
  - Tunneling Tool: used to create a path for the DBS Lead and DBS Extension in the subcutaneous tissue.
  - Lead stop: may be attached to the Lead to prevent the Lead from being advanced beyond a certain depth into the neural tissue during its initial placement.
  - Lead Stylet: inserted in the Lead to keep the Lead stiff during placement.
  - Charging Collar: used to place the Charger externally over the IPG during

charging.

- Charger Spacer: a piece of material placed behind the Charger in the pocket of the Charging Collar.
- Adhesive Kit: for attaching the Charger to the patient's body during charging. Alternative to Charging Collar.
- O.R. Cable and Extension: connects the Lead Extension to the ETS during intraoperative testing.

## VI. ALTERNATIVE PRACTICES AND PROCEDURES

There is no cure for Parkinson's disease (PD) and essential tremor (ET). Therefore, the first-line therapy treatment is medication. The standard medical therapy for PD is levodopa combined with a peripheral decarboxylase inhibitor, such as carbidopa. Other medical therapy may be used as an adjunct to levodopa to treat the multiple symptoms of PD. In patients with ET, both primidone and propranolol reduce the magnitude of upper extremity and postural tremor. Levodopa, anticholinergic medications, dopamine agonists, and beta-blockers such as propranolol are effective drugs for rest tremor. However, these medications come with a variety of side effects. For example, chronic levodopa use can result in disabling motor fluctuations that further impair the patient's ability to function.

Surgical treatments are also available to PD and ET patients. Neurosurgical ablative procedures for the treatment of PD and ET are pallidotomy and thalamotomy. However, there is a risk of permanent neurological damage associated with the irreversible damage caused by these ablation procedures. The most disabling, permanent neurological complications reported include hemiparesis, dysarthria and dysphagia, and cognitive impairment.

Other Deep Brain Stimulation Devices are also currently marketed in the United States.

## VII. MARKETING HISTORY

The Vercise PC and Vercise Gevia DBS Systems have been commercially distributed in the EU since September 2015 and June 2017 respectively. They have been commercially distributed in the US since January 2019. They have also been commercially distributed in other European countries, Canada, Australia, Japan, South America, Middle East, Russia, South East Asia, South Korea, and South Africa.

The Vercise Genus DBS System has been commercially distributed in the EU since May 2020. It has been commercially distributed in the US since February 2021. It has also been commercially distributed in other European Countries, Canada, Australia, Japan, South America, Middle East, South East Asia and South Korea.

The device has not been withdrawn from marketing for any reason related to its safety or effectiveness.

## VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

The adverse events that may occur with the Vercise PC, Vercise Gevia, and Vercise Genus DBS Systems are among those that may occur in association with surgical complications or DBS specific complications (device-related or stimulation-related complications).

For the specific adverse events that occurred in the clinical studies, please see Section X below. Based on the technical equivalence described in Section IX below, the clinically established safety profile of the Abbott Brio Neurostimulation System which was approved under P140009 is directly applicable to the Vercise PC, Vercise Gevia, and Vercise Genus DBS Systems for treatment of essential tremor.

## IX. SUMMARY OF NONCLINICAL STUDIES

### A. Non-clinical Studies

The Vercise PC, Vercise Gevia, and Vercise Genus DBS Systems are legally marketed. Device systems were tested previously via non-clinical laboratory testing, including bench testing, biocompatibility evaluation, electromagnetic compatibility, sterilization, packaging, and shelf-life testing. Device design and system compatibility involved verification and validation of each system. The test results were found to be acceptable.

**Implantable Pulse Generator (IPG)**

**Table 3: IPG Verification Testing**

| Test | Purpose | Acceptance Criteria |
|---|---|---|
| IPG Electronics | Verify the requirements for:<br>• Pulse Generation<br>• Internal IPG circuits<br>• RF Telemetry Interface<br>• Battery Protection Circuitry | • The IPG stimulation output parameters match the programmed parameters within the specified tolerances.<br>• Internal IPG circuits shall function within their specified limits.<br>• The IPG RF receiver shall function as specified.<br>• The battery protection circuits shall function as specified. |
| Environmental and Mechanical Stresses | Verify the integrity and function of the IPG after exposure to environmental and mechanical stress conditions such as:<br>• High and low storage temperature<br>• Temperature changes<br>• Mechanical forces<br>• Random Vibration<br>• High and low atmospheric pressures | The IPG shall pass device level functional tests after exposure to environmental and mechanical stresses. |
| | Verify the integrity of the header after mechanical stresses and suture pull. | Header shall not show visual damage. |
| Hermeticity | Verify that the internal moisture content of the hermetically sealed IPG case is within acceptable limits after environmental stresses. | The internal water vapor content shall be within specifications. |
| Immunity to Medical Procedures /Therapies | Verify that the IPG is functional after exposure to the following medical procedures/therapies:<br>• Diagnostic Ultrasound<br>• Monopolar and bipolar Electrocautery<br>• External Defibrillation<br>• X-Ray | The IPG shall pass device level functional tests after exposure. |

| Test | Purpose | Acceptance Criteria |
|---|---|---|
| IPG-Lead Interface | • Verify that the Lead to IPG connection meets the requirements for insertion, withdrawal and retention forces.<br>• Verify contact resistance.<br>• Verify electrical isolation | • The insertion, extraction and retention forces for the Lead-IPG Connector interface shall meet the specifications after multiple insertion and withdrawal cycles.<br>• The resistance for each contact shall meet the specifications.<br>• The impedance between any two terminations shall be within the specifications. |
| Rechargeable IPG Battery | • Evaluate battery life.<br>• Verify cell performance and integrity. | • The evaluation of battery longevity under typical use conditions shall support the labeled battery life.<br>• After exposure to mechanical and environmental stresses, the battery cells must meet the requirements for hermeticity as well as electrical and mechanical integrity.<br>• The battery cells must meet the requirements for self-discharge and storage loss.<br>• After multiple discharge cycles, battery cells must meet visual, mechanical and hermeticity criteria.<br>• The battery cells shall maintain mechanical integrity during and after application of exposure to short circuits and abnormal discharging. |
| Non-rechargeable IPG Battery | • Evaluate battery life.<br>• Verify cell performance and integrity. | • The evaluation of battery longevity under typical use conditions shall support the labeled battery life.<br>• After exposure to mechanical and environmental stresses, the battery cells must meet the requirements for hermeticity as well as electrical and mechanical integrity.<br>• The battery cells must meet the requirements for self-discharge.<br>• The battery swelling and capacity must meet specifications after discharge.<br>• The battery cells shall maintain mechanical integrity after exposure to short circuits and<br>• forced discharging. |

| Test | Purpose | Acceptance Criteria |
|---|---|---|
| Charging (Vercise Gevia) | • Verify that the IPG can be charged at the specified charging distances and operating temperature.<br>• Verify the requirements for heat generated during charging. | • The IPG charging current and charge time shall meet the requirements when the Charger is at a specified distance from the IPG.<br>• The charge rate over the devices operating temperature shall meet the specifications.<br>• The IPG case heating due to heat dissipation during charging shall be within acceptable limits. |

**DBS Leads, Extensions, and Accessories**

**Table 4: DBS Leads, Extensions, and Accessories Verification Testing**

| Test | Purpose | Acceptance Criteria |
|---|---|---|
| Physical and Mechanical Characteristics | Verify the physical and mechanical characteristics of :<br><br>• Lead<br>• Lead Extension<br>• Stylet<br>• Lead Boot<br>• Lead Stop<br>• Burr-Hole Cover | • Lead dimensions, surface finish, Lead straightness shall meet the specifications.<br>• The distal Lead shall experience minimal movement when the proximal Lead is folded at a specified angle.<br>• The Lead shall withstand the specified end-to-end pull force without loss of mechanical or electrical integrity.<br>• The force required to deflect the Lead tip shall meet the requirements.<br>• When exiting the cannula, deflection of the Lead tip shall be within specification.<br>• The Stylet dimensions and deflection force shall meet the specifications.<br>• The Lead Boot shall meet the requirements for fit, smooth profile, seal and retention force when connected to the lead.<br>• The Lead Stop shall meet the dimensional and geometrical requirements and be able to resist translational forces.<br>• The Burr-Hole Cover shall meet the requirements for dimensions, geometric specifications, lead clip placement and assembly.<br>• The Extension shall withstand tunneling and pull forces.<br>• The Lead and Extension shall maintain mechanical and electrical integrity after exposure to flex fatigue. |

| Test | Purpose | Acceptance Criteria |
|---|---|---|
| Electrical Tests | Verify that the Lead and Extension meets the requirements for electrical isolation and continuity of conductor paths. | • Current leakage shall be within specifications in dry and soaked states.<br>• The electrical DC resistance of the Lead and Extension shall meet the specifications. |
| Interface Tests | Verify the compatibility and interface between Lead, Extension and other Lead accessories. | • The retention force for the connection between Lead, Extension and other Lead accessories shall meet the specifications.<br>• Components shall maintain mechanical and electrical integrity following multiple connection and disconnection cycles between Lead and Lead accessories.<br>• Lead shall maintain integrity after multiple clamp and unclamp cycles with the Burr-Hole Cover. The Lead is securely held in place by the Burr-Hole Cover.<br>• The locking force for the connection between Extension and IPG connector shall meet the specifications. |
| Storage Conditions | Verify integrity of DBS Leads and Sterile Kit components after exposure to temperature conditions likely to be encountered during shipping and storage. | • Components of DBS System Sterile Kits shall be functional after temperature cycling and after storage in high and low temperatures. |

**Remote Control**

**Table 5: Remote Control Verification Testing**

| Test | Purpose | Acceptance Criteria |
|---|---|---|
| Environmental and Mechanical Stress | Verify the integrity and function of the Remote Control after exposure to environmental and mechanical stress conditions such as:<br>• High and low storage temperature<br>• Random Vibration<br>• Drop<br>• Humidity<br>• Button presses representing years of use | The Remote Control shall pass device level functional tests after exposure to environmental and mechanical stresses. |
| Remote Control Functions | Verify Remote Control functions. | • Remote Control shall respond to each key press as well as typically used combinations with appropriate action and appropriate display on the LCD screen.<br>• RF communication with stimulators shall meet the specifications at the labeled distance.<br>• Remote Control shall display the proper battery level status.<br>• Internal circuits shall function as specified |

**Charging System**

The hardware design verification testing was leveraged from the Precision Charger which is the same device as the Vercise Charger.

**Table 6: Charging System Verification Testing**

| Test | Purpose | Acceptance Criteria |
|---|---|---|
| Environmental and Mechanical Stress | Verify the integrity and function of the Charger and Base Station after exposure to environmental and mechanical stress conditions such as:<br>• High and low storage temperature<br>• Temperature changes<br>• Mechanical forces<br>• Random Vibration<br>• Drop<br>• Humidity | The Charger and Base Station shall pass device level functional tests and visual inspection after exposure to environmental and mechanical stresses. |
| Charger Electronics | Verify functionality of the Charger electronics. | • Protection of charging terminals against over- voltage and over- current conditions shall operate as specified.<br>• The quiescent current, coil voltage and frequency, power dissipation and IPG charge current shall meet the specifications.<br>• The Charger electronics shall function as specified with regards to:<br>– indication of battery status level<br>– charging of the Charger battery<br>– indication of alignment with the IPG<br>– detection of end-of-charge signal when IPG is fully charged<br>– battery protection circuits. |
| Heating During Charging | Verify the requirements for heat generated during charging. | • The surface temperature of the Charger shall not exceed the acceptable limit while charging. |
| Base Station | Test for continuity, spring contact fatigue and connector fatigue. | • The resistance between the DC power jack and spring contact shall meet the specifications.<br>• Spring contacts shall remain elastic after repeated deflections.<br>• Power supply plug shall fit and not be loose after repeated<br>• insertion/extraction cycles. |

**External Trial Stimulator (ETS)**

**Table 7: ETS Verification Testing**

| Test | Purpose | Acceptance Criteria |
|---|---|---|
| ETS Electronics | Verify the requirements for:<br><br>• Pulse generation<br>• Operation within the operating temperature range and load range<br>• RF Telemetry Interface | • The ETS stimulation output parameters shall be within the specified tolerances across ranges of temperature and load.<br>• The ETS RF transmitter and receiver shall function as specified. |
| Environmental and Mechanical Stress | Verify the integrity and function of the ETS after exposure to environmental and mechanical stress conditions such as:<br><br>• High and low storage temperature<br>• Random Vibration<br>• Drop<br>• Humidity<br>• Button presses representing years of use | • The ETS shall pass device level functional tests after exposure to environmental and mechanical stresses. |
| ETS - O.R. Cable Interface | Verify that the O.R. Cable to ETS connection meets the requirements for insertion, withdrawal and retention forces. | • The insertion, extraction and retention forces for the ETS-OR Cable Connector interface shall meet the specifications.<br>• Continuity shall be maintained after multiple cycles of insertion and extraction between the OR Cable and ETS |

**Software**
Software testing established that the system meets the software requirements and user needs for the intended uses.

**Electromagnetic Compatibility (EMC) and Wireless Technology**
EMC testing was performed in accordance with the relevant clauses of the following standards and met specified acceptance criteria:

- IEC 60601-1-2: 2014, "*Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*" (appropriate essential performance criteria were used)

- ANSI/AAMI/ISO 14708-3:2017: *Implants for surgery – Active implantable medical devices – Part 3: Implantable neurostimulators"*, Part 27

Testing to address compatibility with Radio-frequency Identification (RFID) and Electronic Article Surveillance systems was also provided.

The wireless technology of the system includes Bluetooth and inductive RF telemetry between the Remote Control and the Stimulators and wireless inductive charging of the IPG. These connections were verified to meet the range, security, data integrity and overall system functionality requirements through design verification testing.

**Biocompatibility**

Biocompatibility of all tissue-contacting components of the Vercise PC, Vercise Gevia and Vercise Genus Deep Brain Stimulation (DBS) System was evaluated in accordance with ISO 10993-1, *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a risk management process*. The Vercise DBS Leads are considered permanent (> 30 days) implants in contact with neural tissue/bone, cerebrospinal fluid (CSF), and blood (indirect contact through CSF). The IPGs, Lead Extensions, Suture sleeves, and Burr-Hole Cover are considered permanent (>30 days) implants in contact with tissue/bone. The Lead Boot is considered an implant device with prolonged (24 hours – 30 days) tissue/bone contact. and implanted accessories meet the biocompatibility requirements for tissue/bone contacting permanent implants per EN ISO 10993-1:2009 COR2010. The Charging Collar is considered an intact skin- contacting device with limited (≤ 24 hours) contact.

Biocompatibility of the Vercise DBS non-directional Leads was demonstrated by cytotoxicity and neuroimplantation testing on the final, sterilized Vercise DBS Leads, leveraging testing previously conducted on the Linear 8 Contact Lead (Model # SC-2138 and SC-2208) approved in P030017, and leveraging biocompatibility data on U.S. marketed devices with direct blood contact. An ISO MEM elution cytotoxicity test was conducted on the Vercise DBS Lead with passing results. A neuroimplantation study was conducted in a swine model to assess the safety of the Vercise DBS Leads at approximately 30- and 180-days post-implantation. Implantation of the Vercise DBS Leads was not associated with any unexpected adverse effects. Both cytotoxicity and implantation studies on the Vercise DBS Leads were conducted in compliance with Good Laboratory Practices (GLP) regulations (21 CFR Part 58). The sensitization, intracutaneous reactivity, systemic toxicity (acute, subchronic, and chronic toxicity), material-mediated pyrogenicity, genotoxicity, and carcinogenicity endpoints for the Vercise DBS Leads were assessed by leveraging biocompatibility information on the Linear 8 Contact Lead (P030017). This was appropriate because the Vercise DBS Leads and Linear 8 Contact Lead are identical in terms of the tissue-contacting materials and are manufactured and sterilized by the same processes. Hemolysis (indirect contact) endpoint was assessed by leveraging hemocompatibility data on the U.S. marketed devices (approved in P010012/S274 and P050046/S012) with identical tissue-contacting materials as the Vercise DBS Leads.

Biocompatibility of the Vercise Cartesia DBS Directional Leads was based on similarity with the Vercise DBS non-Directional Leads. Both Directional and non-

directional Leads have the same tissue-contacting materials and are manufactured and sterilized by the same processes. ISO MEM Elution cytotoxicity and particulate matter release tests were performed on the Vercise Cartesia DBS Directional Leads with passing results. In addition, a neuroimplantation study was conducted in a swine model to assess the safety of the Vercise Cartesia DBS Directional Leads at approximately 90 days post-implantation. Implantation of the Vercise Cartesia DBS Directional Leads was not associated with any unexpected adverse effects.

Biocompatibility of the Vercise PC, Vercise Gevia and Vercise Genus IPGs was demonstrated by leveraging testing previously conducted on the Precision Novi, Precision Spectra and Precision Montage SCS System IPG Models SC-1140 (P030017/S217, S287), SC-1132 (P030017/S134, S245) and SC-1200 (P030017/S235) respectively. Leveraging this testing information was appropriate because the Vercise PC, Vercise Gevia and Vercise Genus IPGs are identical to the Precision SCS System IPGs in terms of the tissue-contacting materials, manufacturing including sterilization processes, and the nature and duration of tissue contact.

The Vercise Lead Extensions are the same lead extensions used in the Precision SCS System (P030017).

Biocompatibility of the Vercise Suture Sleeves was demonstrated by appropriately leveraging testing previously conducted on Linear 8 Contact Lead (Model # SC-2138 and SC-2208) approved in P030017. The Vercise Suture Sleeves are made of the identical silicone material that is present in the Linear 8 Contact Lead and both devices have permanent (> 30 days) contact with tissue/bone. In addition, an ISO MEM elution cytotoxicity test was conducted on the finished, sterilized 4.0 cm Vercise Suture Sleeve with passing results.

The Burr Hole Cover consists of a Base, Retaining Clip, Cap and two Screws. Biocompatibility of the Base, Retaining Clip, and the Cap was demonstrated by testing conducted on these components in their finished, sterilized forms and by leveraging data in the device master file and in the US marketed devices with identical material. The MEM elution cytotoxicity, guinea pig maximization sensitization, intracutaneous reactivity, intramuscular implantation (13 weeks), acute systemic toxicity, rabbit pyrogenicity, and genotoxicity (Ames, in vitro chromosomal aberration, and mouse micronucleus) tests were conducted on the Base, Retaining Clip, and Cap. All biocompatibility tests were conducted in compliance with GLP regulations (21 CFR Part 58). All pre-specified test acceptance criteria were met for all tests and all tests passed. The data in the device master file and the US marketed devices were leveraged for the assessment of subchronic/chronic toxicity and carcinogenicity endpoints.

Biocompatibility of the Screws was demonstrated by appropriately leveraging biocompatibility data on Precision SCS System IPG Model SC-1110 (P030017) with identical material and nature and duration of tissue contact. In addition, the final, sterilized Burr Hole Cover was used in the swine neuroimplantation study (30 and 180 days) and no device material related adverse findings were noted in thestudy.

Biocompatibility of the Vercise Lead Boot was demonstrated by leveraging testing previously conducted on the Precision SCS System 55cm 8 Contact Lead Extension (Model SC-3138-55) approved under P030017. Leveraging this testing information was appropriate since the Vercise Lead Boot is identical to the Precision SCS System 55cm 8 Contact Lead Extension (Model SC-3138-55) in terms of the tissue-contacting materials, manufacturing and sterilization processes. In addition, an ISO MEM elution cytotoxicity assay was conducted on the finished, sterilized Vercise Lead Boot with passing results.

Biocompatibility testing was conducted on the finished DBS Charging collar in accordance with GLP regulations (21 CFR Part 58). The agarose overlay cytotoxicity assay, primary skin irritation, and repeated patch dermal sensitization tests were conducted on the DBS Charging Collar, All pre-specified test acceptance criteria were met for all tests and all tests passed.

**Sterilization**
The IPGs, DBS Lead, Extension, OR Cable, Burr Hole Cover and other implanted accessories are sterilized using a validated EO sterilization cycle to achieve a minimal sterility assurance level of $10^{-6}$. Validation of the EO sterilization process for these devices was done in accordance with EN ISO 11135:2014 *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*. EO residual levels found on these devices following EO sterilization process are shown to be below the maximum allowable limits of EO and Ethylene chlorhydrin (ECH) residual levels specified in EN ISO 10993-7:2008(Cor) 2009 *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals.*

The bacterial endotoxin levels on these device, determined using Limulus Amebocyte Lysate (LAL) testing in accordance with the USP Chapter <161> *Transfusion and Infusion Assemblies and Similar Medical Devices*, and ANSI/AAMI ST72:2011 *Bacterial endotoxins - Test methods, routine monitoring and alternatives to batch testing*, comply with the bacterial endotoxin limits specified in the and FDA's Guidance for Industry - Pyrogen and Endotoxins Testing: Questions and Answers (June 2012).

**Packaging and Shelf Life**
Packaging performance and stability testing results demonstrated that the packaging system for the sterile components of the BSN Vercise PC, Vercise Gevia and Vercise Genus DBS Systems can withstand the environmental and mechanical stresses likely to be encountered during transportation and storage and maintain its sterile barrier up to two years of the established shelf-life.

## B. Technological Comparison

In lieu of providing a clinical data set for treatment of essential tremor with the Vercise PC, Vercise Gevia and Vercise Genus DBS Systems, the sponsor provided a technological comparison (including a comparison of the technology, and instructions for use) of the Vercise PC, Vercise Gevia and Vercise Genus DBS Systems to the Abbott Brio Neurostimulation System which was approved under P140009 for the

requested indications for use. The purpose of the technological comparison was to establish sufficient similarity of the Boston Scientific and Abbott DBS devices such that FDA could apply Section 216 of the Food and Drug Modernization Act (FDAMA), i.e., the "six-year rule," to assess the effectiveness profile of Vercise PC, Vercise Gevia and Vercise Genus DBS Systems.

According to FDA's "Guidance on Section 216 of the Food and Drug Modernization Act of 1997" available at: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073709.pdf, FDA may choose to utilize the publicly available detailed SSED of a previously approved device to support approval of a PMA for a new device if the applicant provides "a detailed justification of how the information in the earlier SSED applies to the applicant's device" and if the applicant is able "to describe how the devices are similar enough to allow for the data from the earlier device to apply to the new device."

For the purposes of establishing sufficient similarity of the Vercise PC/Vercise Gevia/Vercise Genus DBS Systems and the Abbott Brio Neurostimulation System, the sponsor provided a technical comparison of the devices. The comparisons are summarized as follows:

1. Volume of Tissue Activation (VTA)

   Deep brain stimulation (DBS) systems work by sending electrical stimulation from an implanted neurostimulator to leads in the brain where the current is dispersed through electrodes into the brain tissue in order to activate neurons in specific brain regions. The clinical response of stimulation varies depending on the brain target and the orientation of the DBS lead within the target. As part of DBS programming, the clinician can adjust the combination of parameters, including amplitude, pulse width, frequency and electrode configuration, to tailor the stimulation field to the needs of each patient. By comparing the VTA of the Vercise PC, Vercise Gevia and Vercise Genus DBS Systems to the Abbott Libra and Brio Neurostimulation Systems, it was determined that the Vercise DBS Systems stimulate, and thus activate, neurons with volume of brain tissue equivalent to that which was shown to be safe and effective for the Abbott Brio Neurostimulation System approved in P140009.

   VTA modeling has been used to estimate the degree of neuronal activation and by extension the degree of stimulation efficacy [1]. Thus, the sponsor provided comparative modeling of the VTA between the stimulation produced by Vercise PC/Vercise Gevia/Vercise Genus DBS System IPGs and the associated non-directional (DB-2201) and directional (DB-2202) leads and the Abbott Libra and Brio Neurostimulation Systems with the Abbott leads (Model 6142, 6143, 6144, 6145, 6146, 6147, 6148, and 6149). The Brio Neurostimulation System was approved for essential tremor in P140009. The Libra IPG was used in the clinical trials for the approval of the treatment of essential tremor under P140009. The VTA modeling provided comparing ABT and BSN leads is applicable to either the Libra or Brio IPG.

The electric fields generated during stimulation via the DBS electrodes were calculated from the Poisson equation with a finite element model (FEM) solver to determine space-dependent voltage within the neural tissue medium [1, 2]. Finite element models were constructed to calculate the electric fields produced by DBS leads in a homogenous tissue medium, and the calculated voltages in space were applied to non-linear axon models in accordance with methods described in the literature for evaluation of DBS electrode design and characterization of field shape [1,2]. There are no differences in assumptions and boundary conditions between the previous modeling papers and the modeling data presented by the sponsor.

The Boston Scientific Vercise PC, Vercise Gevia and Vercise Genus IPG waveform includes a current regulated stimulation phase and is passively charged balanced, equivalent to the Abbott Libra and Brio waveforms. The waveform was accounted for in this modeling. The waveform was measured from the Vercise IPG and the components of the waveform were fed into the model, in addition to appropriate electrode geometry, including edge-to-edge spacing, array length, electrode surface area, and electrode configuration. The following output stimulation parameters were used as the basis for the input parameters for the model: amplitude, pulse width and stimulation mode (monopolar or bipolar). The sponsor consulted literature (Koller et al, 2001) and data reported for clinical trials for the Abbott Libra Neurostimulation System as described in the SSED for P140009 and chose values representative of the ranges of parameters reported. The sponsor chose combinations of parameters to create low and high nominal values as typically used parameters for VIM stimulation in Tremor (i.e., 1.5 – 5.0 mA, 60 – 120 μs). The following scenarios were modeled for the Abbott leads and the Boston Scientific 8 channel non-segmented (DB-2201) and segmented (DB-2202) leads, where current was titrated to achieve a comparable VTA:

**Table 8: Parameters Used in Models of the Abbott Model 6142 and 6146 VTAs compared to BSN DB-2201 and DB-2202**

| Test Case | ABT Lead | Polarity | Amplitude (mA) | Pulse Width (μs) | BSN Lead |
|---|---|---|---|---|---|
| 1 | 6142 | Cathodic Monopolar | 1.5 mA<br>5.0 mA | 60 μs<br>120 μs | DB-2202 |
| 2 | 6146 | Bipolar | 1.5 mA<br>5.0 mA | 60 μs<br>120 μs | DB-2202 |
| 3 | 6142 | Bipolar | 1.5 mA<br>5.0 mA | 60 μs<br>120 μs | DB-2201 |
| 4 | 6142 | Cathodic Monopolar | 1.5 mA<br>5.0 mA | 60 μs<br>120 μs | DB-2202 |

A total of 16 unique VTAs were compared in combination for both Abbott and Boston leads. For the Abbott lead, 8 unique VTAs listed in Table 8; the Monopolar configurations were modeled for both ABT electrode '1' and

electrode ‘4’. For each Boston Scientific lead, 8 unique VTAs were modeled, corresponding to Table 8 settings, resulting in 8 total Boston Scientific VTAs. These VTAs represented relevant output parameters, configurations, and lead types (non-directional (non-segmented) and directional (segmented)). The scenarios were created to demonstrate the capability of both the Boston Scientific Vercise 8-contact non-directional lead (DB-2201) and the Boston Scientific Vercise Cartesia 8-contact directional lead (DB-2202) to produce a VTA comparable to that produced by the Abbott 6142 and 6146 4-contact leads. Then for each Abbott VTA, amplitude was titrated with the Boston Scientific DB-2201 and DB-2202 leads to achieve a VTA comparable to that achieved by the Abbott lead.

Results:
The modeled Boston Scientific leads were able to achieve a comparable VTA volume and shape when compared the Abbott lead.

In all the scenarios above the percent deviation of the VTAs of the Boston Scientific leads from the VTA of the Abbott lead ranged between **3.14%** (meaning greater coverage for Boston Scientific leads) and **-6.21%**.

Conclusions:
The results show that parameters of the Vercise PC, Vercise Gevia and Vercise Genus DBS Systems can be varied to achieve a VTA comparable to that achieved by the Abbott Libra and Brio Neurostimulation Systems (latter approved in P140009); the range of deviation is acceptable. These results also demonstrate that a desired VTA can be achieved by adjusting stimulation parameters on any of the lead models (Boston Scientific lead models DB-2201 and DB-2202, Abbott lead model families of 6142 and 6146).

The clinical response to stimulation varies depending on the brain target and the position and orientation of the DBS lead within the target. As part of DBS programming, the clinician can adjust the combination of parameters, including amplitude, pulse width, frequency, and electrode configuration, to tailor the stimulation field to the needs of each patient. Parameters can be adjusted to achieve a desired VTA, with shaping customized on a patient-by-patient basis.

2. Output Parameters

**Table 9: Device Comparison Summary Table of the Abbott Libra IPG and Brio IPG (Model 6789) to Vercise PC, Vercise Gevia and Vercise Genus DBS System IPGs**

| | Vercise PC / Gevia / Genus | Libra | Brio | Safety | Efficacy |
|---|---|---|---|---|---|
| Amplitude (settings) | 0 - 12.7 mA per contact (max 20.0 mA per area) | 0 - 12.75 mA | 12.75 mA max at 500Ω | Both confined by charge density limit 30 μC/cm$^2$). Parameters verified via Boston Scientific Parkinson's study to be safe for use in the STN which is also relevant to the VIM. | Equivalent parameter ranges. |
| Frequency (settings) | 2 - 255 Hz | 2 – 240 Hz | 2-240 Hz | Parameters verified via the Boston Scientific Parkinson's Study to be safe for use in the STN which is also relevant to the VIM. | Can be programmed within clinically relevant parameter ranges, wider ranges that are available through BSN IPGs provide additional programming flexibility. |
| Pulse width (settings) | 20 – 450 μsec | 52 - 507 μsec | 50-500 μsec | Both confined by charge density limit 30 μC/cm$^2$). | Can be programmed within clinically relevant parameter ranges, wider ranges that are available through BSN IPGs provide additional programming flexibility. |
| Number of Programs | 4 | 1 | 1 | All programs created must be within the available safe parameters. | Can be programmed within clinically relevant parameters, additional parameters provide programming flexibility |

| | Vercise PC / Gevia / Genus | Libra | Brio | Safety | Efficacy |
|---|---|---|---|---|---|
| Independent Frequency/ Hemisphere | Yes | Single channel, 8 contact system | No, both leads are required to have the same frequency setting | All programs created must be within the available safe parameters. | Can be programmed within clinically relevant parameters, additional parameters provide programming flexibility |
| Stim on/off | 1 seconds – 90 minutes | Unknown | Cycling is allowed but allowable parameters are not provided | BSN Stimulators ensure charge balance condition for all settings. | Can be programmed within clinically relevant parameters. |
| Waveform – charge balance method | Charge balanced biphasic | Charge balanced biphasic | Charge balanced biphasic | Equivalent waveform methods | Equivalent waveform methods |
| Pulse Shape | Rectangular | Rectangular | Rectangular | Same | Same |
| Charge balance | Passive discharge | Passive discharge | Passive discharge | System requirements have been incorporated into the product design to ensure that stimulation pulses are balanced with appropriate discharge. | Waveform shown to be effective in eliciting and inhibiting action potentials as shown in approval for STN stimulation which is also grey matter. |
| Pulse delivery modes | Continuous and Cycle` | Continuous and Cycle | Continuous and Cycle | System requirements have been incorporated into the product design to ensure that stimulation pulses are balanced with appropriate discharge. | Continuous and cycling effective in eliciting and inhibiting action potentials cycling can help prevent habituation |

| | Vercise PC / Gevia / Genus | Libra | Brio | Safety | Efficacy |
|---|---|---|---|---|---|
| Current distribution to electrodes | Stimulators control the amount of current at each electrode independently during a stimulation pulse | Single source current control | Single source current control | Stimulation is delivered at clinician prescribed stimulation settings over time. | Impedance changes do not affect stimulation delivery. The prescribed current is maintained at each electrode regardless of impedance changes. |
| Current or Voltage Regulated | Current | Current | Current | Same | Same |

The table above demonstrates that the Vercise PC, Vercise Gevia and Vercise Genus DBS Systems have the capability to replicate at least the same output as the Abbott Libra and Brio Neurostimulation Systems indicating it can provide at least a comparable level of efficacy. The degree of neuronal activation with DBS is proportional to the amount of charge delivered. The intensity of the charge delivered (charge density) also has implications for clinical safety. For parameters that differ between the devices, Table 9 above shows that the Vercise PC, Vercise Gevia and Vercise Genus DBS Systems ensure safety by providing a charge density limit (30 $\mu C/cm^2$) and preventing charge imbalance conditions. As the electrode surface area of the Boston Scientific DBS Leads is less than or equal to that of the Abbott Leads, the maximum charge at the charge density limit is less than or equal to the Abbott system. The maximum power and power density is limited by the charge density limit.

The Boston Scientific INTREPID Parkinson's study of STN stimulation provides further assurance of the safety of the additional parameters provided by the Vercise PC, Vercise Gevia and Vercise Genus devices. The study was used to support the safety of DBS at therapeutic levels for Parkinson's disease. Although patients in the study were implanted in the STN, both STN and VIM are grey matter nuclei that can be stimulated to treat some of the symptoms of Parkinson's disease.

3. Leads

See VTA analysis in Section IX(B)(1) above. Table 10 below provides an additional comparison of Lead attributes.

**Table 10: Comparison between Vercise PC, Vercise Gevia and Vercise Genus DBS System Leads and Abbott Neurostimulation System Leads**

| | Boston Scientific DBS Leads | | Abbott DBS Lead Models 6142, 6143, 6144, 6145, 6146, 6147, 6148, 6149 | Clinical Equivalence |
|---|---|---|---|---|
| | Standard 8-contact DBS Lead Model DB-2201 | Directional 8-contact DBS Lead Model DB-2202 | | |
| **Electrode configuration** | 1-1-1-1-1-1-1-1<br>  <br>8 electrode configuration, no active tip | 1-3-3-1<br>  <br>8 electrode configuration, active tip | 1-1-1-1 | See VTA analysis in Section IX(B)(1). Additionally, the Directional Lead has the same stimulation output capabilities with additional programming options.<br>1st and 4th contact rows provide omnidirectional stimulation.<br>2nd and 3rd rows can use all 3 segments to provide omnidirectional stimulation that is clinically equivalent or use segmented electrodes |
| **Active tip** | No | Yes | Yes | The presence of Active Tip at the tip of the Directional array (contact 1), results in one contact (tip) with the same larger surface area as the other ring contacts. From a stimulation efficacy perspective, the clinical response of stimulation varies depending on the brain target and the orientation of the DBS lead within the target. See VTA analysis in Section IX(B)(1). |
| **Electrode material** | Platinum/Iridium | Platinum/Iridium | Platinum / Iridium | Same |
| **Lead Body** | Polyurethane | Polyurethane | Polycarbonate Urethane | All leads are made up of biocompatible materials. The minor differences in materials have no impact on the biological safety or function of these leads. |

| | Boston Scientific DBS Leads | | Abbott DBS Lead Models 6142, 6143, 6144, 6145, 6146, 6147, 6148, 6149 | Clinical Equivalence |
|---|---|---|---|---|
| | **Standard 8-contact DBS Lead Model DB-2201** | **Directional 8-contact DBS Lead Model DB-2202** | | |
| **Electrode Surface area** | 6 $mm^2$ | Ring electrodes: 6 $mm^2$<br><br>Segmented electrodes: 1.5 $mm^2$ | 12.7$mm^2$ (electrode 1) 6.42$mm^2$ (electrode 2-4) | See VTA analysis in Section IX(B)(1). |
| **Number of electrodes** | 8 | 8 | 4 (1 tip electrode, 3 ring electrodes) | See VTA analysis in Section IX(B)(1). |
| **Contact length (mm)** | 1.5 | 1.5 | 3mm tip electrode<br><br>1.5mm ring electrodes | See VTA analysis in Section IX(B)(1). |
| **Contact spacing (mm)** | 0.5 | 0.5 | 0.5 and 1.5 | See VTA analysis in Section IX(B)(1). |
| **Array length (mm)** | 15.5 | 7.5 | 9 or 12 | See VTA analysis in Section IX(B)(1). |
| **Leads length (cm)** | 30, 45 | 30, 45 | 25, 30, 35, 40 | Lead length does not impact the delivery of stimulation to the targets. |
| **Lead diameter (mm)** | 1.3 | 1.3 | 1.4 | See VTA analysis in Section IX(B)(1). |

As outlined in Table 10 above, the Vercise PC, Vercise Gevia and Vercise Genus DBS System and the Abbott Neurostimulation System Leads are clinically equivalent. Although there are differences in some physical aspects of the Leads, those differences have been demonstrated not to impact the safe and efficacious delivery of the stimulation to the targeted location.

4. Extensions

The table below shows a comparison between attributes of the Boston Scientific DBS Extension and the Abbott Extension.

**Table 11: Comparison between Boston Scientific DBS System Extension and Abbott Neurostimulation System Extensions**

| | **Boston Scientific DBS Extension Models NM-3138-xx and DB-3128-xxB** | **Abbott DBS Extension Models 6345, 6346** | **Clinical Equivalence** |
|---|---|---|---|
| Body diameter (mm) | 1.35 or 1.31 | 1.4 | The diameter does not impact the delivery of electrical stimulation to the target location through the lead contacts. |
| Body construction | Continuous | Continuous | The body construction for both extensions is continuous and therefore they are clinically equivalent. |
| Lengths (cm) | 55, 95 | 50 or 60 | The additional lengths offered for the Boston Scientific Extensions are available for physicians to use as appropriate for different patient anatomies and do not impact safety and effectiveness of the system as the delivery of effective stimulation is not impacted by the length of the Extension. |
| Number of distal (lead) contacts | 8 or 2x8 | 4 | The variance in the number of contacts is a function of the actual Lead with which the Extension is used. For example, an 8-contact Lead would require 8 distal contacts in order to adequately connect to the Extension and deliver therapy from the IPG to the target location.<br>The difference is the number of contacts does not impact safety and effectiveness because the stimulation can be effectively transmitted along the Extension regardless of the number of contacts. |
| Locking mechanism | 1 setscrew | 1 setscrew | Locking mechanisms are designed and tested to provide adequate retention force of the Lead within the Extension header. |
| **Patient Contacting Materials** | | | |
| Extension | Silicone, Polyurethane | Platinum iridium, silicone elastomer, polycarbonate urethane | The Extension is made up of biocompatible materials. The minor differences in materials have no impact on the biological safety or function of the Extension. |

As outlined in Table 11 above, the Vercise PC, Vercise Gevia and Vercise Genus DBS System and the Abbott Neurostimulation System Extensions are clinically equivalent. Although there are differences in some physical aspects of the Extensions, those differences have been demonstrated not to impact the safe and efficacious delivery of the stimulation to the targeted location.

5. Accessories

Since IPGs, Leads and Extensions play a direct role in the delivery of therapy to patients, detailed equivalence assessments (technical, biological and clinical) are provided. However, the assessment of PMA approved system accessories is focused on how each accessory functions and contributes to the effective delivery of therapy, including how its dimensions, materials and mechanical properties allow it to safely perform that function. Table 12 below provides this comparison and establishes that there are no differences that impact the safety and effectiveness of the respective systems during use for a VIM target location.

**Table 12: Comparison between Vercise PC, Vercise Gevia and Vercise Genus DBS System accessories and Abbott Neurostimulation System accessories**

| Accessories Name | Vercise PC / Gevia / Genus | Libra and Brio | Function | Clinical Equivalence |
|---|---|---|---|---|
| **IPG Implant Accessories** | | | | |
| Torque Wrench | Yes | Yes | Secure the Extensions in the IPG | The mechanical properties and dimensions are compatible with the IPG/Lead to safely ensure system performance (e.g. lead connection to IPG) |
| Port Plug | Yes | Yes | Prevent tissue and fluid ingress into unused ports | The mechanical properties and dimensions are compatible with the IPG to safely ensure system performance (e.g. IPG port enclosure). From a material perspective, port plugs are considered biocompatible for their intended use per ISO 10993. |
| Patient Magnet | No | Yes | Used to perform magnet enabled functions on the IPG | The Vercise PC, Gevia and Genus IPGs do not have any magnet enabled functions other than to put the Genus IPG in pairing mode for the initial pairing of the IPG to the Remote Control. The absence of a patient magnet does not impact clinical safety or performance. |

| Accessories Name | Vercise PC / Gevia / Genus | Libra and Brio | Function | Clinical Equivalence |
|---|---|---|---|---|
| Pocket Template | Yes | Yes (Pocket sizer) | Create an IPG implant site that is appropriate for the IPG size | The dimensions match the dimensions of the IPG for use during the implant procedure.<br>From a materials perspective the Pocket Templates are considered biocompatible for their intended use per ISO 10993. |
| **External Trial Stimulator Accessories** | | | | |
| OR Cable | Yes | Yes | Connects Lead or Extension to an External Stimulator to evaluate lead placement location and integrity during the procedure | The dimensions and mechanical properties are compatible with the External Stimulator and Leads to safely ensure system performance (e.g. via electrical connection). From a material perspective the OR Cables are considered biocompatible for their intended use per ISO 10993. |
| **Lead Surgical Accessories** | | | | |
| Lead Stop | Yes | Yes | To mark the depth of the Lead during implantation. | The mechanical properties and dimensions are compatible with the Leads to safely ensure system performance (e.g. marking a specific position on the Lead). From a material perspective, the Lead Stop is considered biocompatible for its intended use per ISO 10993. |
| Lead Boot | Yes | Yes | To protect the electrodes from damage. | The mechanical properties and dimensions are compatible with the Leads to safely ensure system performance (e.g. isolation and protection of the Lead). From a material perspective, the Lead protection boot is considered biocompatible for its intended use per ISO 10993. |
| Burr Hole Cover | Yes | IFU references using a burr hole cover system or equivalent | To permanently secure the DBS Lead and to cover the burr hole created in the skull during the surgical implantation of the DBS Lead. | The mechanical properties and dimensions are compatible with the Leads to safely ensure system performance (e.g. secure the Lead). From a material perspective, the Burr Hole Cover is considered biocompatible for its intended use per ISO 10993. |

| Accessories Name | Vercise PC / Gevia / Genus | Libra and Brio | Function | Clinical Equivalence |
|---|---|---|---|---|
| Suture Sleeves | Yes | No | Used to protect the Lead when using a miniplate. May also be used to anchor the DBS Lead or DBS Extension to the fascia. | The mechanical properties and dimensions are compatible with the Leads to safely ensure system performance (e.g. secure the Lead). From a material perspective, the Suture Sleeves are considered biocompatible for its intended use per ISO 10993 |

6. Remote Control/Therapy Controller capabilities

The BSN Remote Control and Brio Patient Programmer, Model 6860 allows the patient to check the status of their IPG (On/Off, battery levels, etc.), adjust the stimulation amplitude within limits set by the physician, and turn stimulation On or Off.

The Vercise PC/Gevia/Genus Remote Controls have an additional capability to switch between up to 4 programs, as set by the physician in the Clinician Programmer. This additional capability does not affect the therapy as prescribed by the physician.

7. Labeling

The instructions for use are equivalent regarding implant procedures, stimulation related device programming (see Table 9 above) and other instructions for use. The devices also have equivalent labeling for contraindications, warnings, precautions, and adverse events.

## X. SUMMARY OF PRIMARY CLINICAL STUDIES

### A. Summary of Study to Support Approval of the Abbott Brio Neurostimulation System approved in P140009

Because of the technological similarity of the Vercise PC, Vercise Gevia and Vercise Genus DBS Systems to the Abbott Brio Neurostimulation System approved under P140009, as described in Section IX above, the clinical studies used to provide evidence of the reasonable assurance of the safety and effectiveness of the Abbott Brio Neurostimulation System under P140009 apply equally well to the Vercise PC, Vercise Gevia, and Vercise Genus DBS Systems. The clinical studies used to establish reasonable assurance of the safety and effectiveness of the Abbott Brio Neurostimulation System are summarized as follows. Additional details of these studies are provided in the SSED for P140009 that is available on the CDRH website.

Abbott performed a clinical study to establish a reasonable assurance of safety and effectiveness of the Abbott Deep Brain Stimulation (DBS) System for the treatment of essential tremor of the upper extremities. A total of 150 patients with disabling medication refractory upper extremity essential tremor were enrolled from 12 investigational sites. A total of 127 patients were implanted with Abbott DBS Systems.

The study was designed as a prospective, multi-centered study for 365 days in duration from device implantation. The duration for the original study was for one year. After one year, patients were consented to the Long-Term Follow-Up Study where they continued follow-up for a total follow-up duration of 5 years post-implant.

The primary effectiveness endpoint was the difference in the postural or kinetic tremor score of the target limb between stimulation On and stimulation Off at the 180-day visit. Postural and kinetic tremor scores were assessed by the Clinical Rating Scale for Tremor (CRST). There was no control group in this study. The primary analysis was evaluated by one independent blinded reviewer. At Baseline and Day 180, the CRST evaluation session was video recorded for analysis by an independent evaluator unaware of the functioning of the device (i.e., the evaluator did not know if the patient on the video was being assessed at the baseline visit prior to the device implant or at the Day 180 visit after implantation and whether the device was on or off at that assessment.

The primary safety endpoint analysis compared the rate of device-related or procedure related adverse events within 6 months post-implant compared to a historical control of 38.1%. The secondary safety analysis summarized the rates of time to first device related or procedure related adverse events within 6 months of the initial unilateral implant using one-sided 95% upper confidence bounds.

## B. Results Used to Establish Reasonable Assurance of Safety of Vercise PC, Vercise Gevia and Vercise Genus Systems for Treatment of Essential Tremor

1. Safety Results for P140009: Essential Tremor Study

   The analysis of safety was based on the 127 patients implanted in the trial. The safety profile was based on a comparison of adverse events that occurred through the 180-day period following implant to a historical control, as well as a comparison of all adverse events that occurred through the last follow-up visit.

   Forty patients (31.5%) had a device or procedure-related adverse event that occurred within 180 days of the initial implant. A total of 55 adverse events occurred in the first 180 days of initial implant and prior to second implant. The most common adverse event reported in the first 180 days was jolting or shocking sensations.

   A total of 327 adverse events in 97 (76%) subjects occurred during the study which included 34 serious adverse events in 29 patients. The events included 8 infections, 3 intracranial hemorrhages, 2 paresis, 1 seizure and 1 stroke. There were 2 deaths related to cardiac events and 1 death was due to unknown causes. No unanticipated device effects occurred during the study.

   Thirty-nine (39) patients had their second side implanted approximately 180 days after the first side implant. The most common adverse event report after the second side was dysarthria with 9 (7%) patients reporting.

   Details of the safety results are provided in the SSED for P140009 that is available on the CDRH website.

2. Safety Results for P150031 INTREPID Study

   The Implantable Neurostimulator for the Treatment of Parkinson's Disease (INTREPID) Study is a multi-center, prospective, double-blind, randomized, controlled study performed by Boston Scientific that was design to evaluate the safety and effectiveness of the Vercise DBS System for bilateral stimulation of the STN as an adjunctive therapy for improving dyskinesia and other symptoms in adults with advanced, levodopa-responsive bilateral Parkinson's disease which is not adequately controlled with medication. This study was used to support approval of the Vercise DBS System under P150031. Additional details of this study are provided in the SSED for P150031 that is available on the CDRH website. The Vercise PC, Vercise Gevia, and Vercise Genus DBS Systems were approved under P150031/S001 and P150031/S034 based on a similarity of technological characteristics to the Vercise DBS System. Although the data were used to support the safety of DBS at the STN, findings have applicability to the safety of stimulation at the VIM since the STN and VIM are both grey matter nuclei and the technological characteristics are similar. Stimulation related adverse effects typically can be resolved at either of the grey matter locations by adjustments to stimulation parameters.

   The initial epoch of the study was a period of 12 weeks during which subjects remained blinded to their treatment assignment, and during which a blinded assessor (who was unaware of the subject assignment) completed all study assessments (i.e., double blind

study design). Subjects were randomized in a 3:1 ratio to either receive Active or Control settings. Subjects in the Active group received therapeutic settings titrated by the treating neurologist to best clinical effect. Subjects in the Control group received sham stimulation where the stimulation was not set to therapeutic levels. At the Week 12 post-randomization visit, all subjects began an open-label period, with a follow-up period up to 5 years.

The primary safety endpoint of the study included the rates of occurrence of pre-specified adverse device effects at 52 weeks post-randomization. Additional safety parameters evaluated in the study included the rates of occurrence of all serious adverse events and all adverse device effects, including serious adverse device effects and unanticipated adverse device effects at 5 years post-randomization.

The data used in consideration of PMA P150031 reflected data collected through December 31, 2016, and included 292 patients from 23 investigational sites. A total of 788 adverse events in 143 subjects were reported at the time of the data snapshot. Of these, 74 events were reported as serious adverse events. Of 74 serious adverse events, 19 were related to hardware, 2 related to stimulation, and 31 related to procedure. Infection has been the most commonly reported serious adverse event associated with device-hardware/procedure (8 events, representing 2.7% of subjects). There were three events (each) of device-hardware/procedure- related serious adverse events of peri-operative intracranial hemorrhage (representing 1% of subjects) and seizure (representing 1% of subjects). These events are comparable to published reports.

## C. Results Used to Establish Reasonable Assurance of Effectiveness of Vercise Gevia and Vercise Genus Systems for Treatment of Essential Tremor

Effectiveness Results for P140009: Essential Tremor Study

The analysis of effectiveness was based on the 127 evaluable patients at the 180-day time point.

*Primary Endpoint:*

The primary effectiveness endpoint was based on the postural tremor score of the target limb between stimulation On and stimulation Off, at the Day 180 visit, as measured by the blinded reviewer. Among the 127 implanted patients, 118 had site physician assessments at 180 days. Among these 118 patients, 87 had blinded assessments with stimulation Off and 86 had blinded assessments with stimulation On for the primary endpoint at 180 days, resulting in 76 patients with data for both stimulation On and stimulation Off. The mean difference at Day 180 in the postural tremor CRST score of the target limb between stimulation On and stimulation Off was -1.25 ± 1.26 which is statistically significant ($p<0.001$).

*Secondary Endpoints:*

The following secondary endpoints were also assessed at 180 days and 365 days:

– The mean difference in the target limb severity score from baseline (as measured on the CRST scale) at each study visit was -2.34 at 90 days, -2.42 at 180 days and -2.48 at 365

days. Additionally, target limb severity scores were compared between stimulation On and stimulation Off at each visit, by the site physician. The mean difference between stimulation On and stimulation Off at each visit was -1.66 at 90 days, -1.74 at 180 days and -1.94 at 365 days.

- 98/118 (83.1%) of patients had success with DBS treatment. Success was defined as those patients who have a minimum of a 2-point reduction in postural or kinetic tremor scores and show an improvement in activities of daily living at 180 days.
- For patients with bilateral stimulation, the decrease in the mean non-target limb severity score from baseline was -1.87 at 180 days. Additionally, non-target limb severity scores were compared between stimulation On and stimulation Off after 180 days of stimulation, by the site physician. The mean difference between stimulation On and stimulation Off was -1.72.
- For bilateral stimulation patients who had only the second side system turned on, the decrease in the mean non-target limb severity score from baseline was -1.73 at 180 days. Additionally, non-target limb severity scores were compared between stimulation On and stimulation Off after 180 days with only the second side system on, by the site physician. The mean difference between stimulation On and stimulation Off was -1.62.
- 29/43 (67%) of the patients with bilateral implants had a 2 point reduction in tremor scores and an improvement in ADLs (Activities of Daily Living) at 6 months.
- Stimulation achieved a positive improvement on motor symptoms. The mean overall motor score (as measured by CRST) change from baseline at Days 180 and 365 were -9.4 and -9.3 respectively.
- Stimulation achieved a positive improvement on a patient's activities of daily living. The ADL score had a mean decrease of -11.1 at Day 180, and a mean decrease of -11.5 at Day 365 from baseline. In addition, the mean difference between stimulation ON and stimulation OFF was -9.1 at Day 180, and -10.0 at Day 365.
- Stimulation improved a patients Quality of Life as assessed by the QUEST and SF-36 questionnaires at Day 365.
- Improvements were observed in both Patient and Caregiver Global Assessment of Change.
- 98/110 (89%) of the patients very satisfied or satisfied by the DBS Systems functioning and ability to control symptoms.

## D. Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

## E. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation.

The pivotal clinical study for the Boston Scientific Vercise DBS System included 48 investigators of which none were full-time or part-time employees of the sponsor and only one had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: none
- Significant payment of other sorts: one investigator
- Proprietary interest in the product tested held by the investigator: none
- Significant equity interest held by investigator in sponsor of covered study: none

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. The information provided does not raise any questions about the reliability of the data.

The pivotal clinical studies for the Abbott Neurostimulation System under P140009 included 13 investigators. None of the clinical investigators had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

## XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Neurological Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

## XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

### A. Conclusions Drawn from Nonclinical Studies

The Vercise PC and Vercise Gevia DBS Systems were approved for stimulation of the STN and GPi for the treatment of Parkinson's disease in P150031/S001 and P150031/S028. The Vercise Genus DBS System was approved for stimulation of the STN and GPi for the treatment of Parkinson's disease in P150031/S034. All three systems were approved for unilateral stimulation of VIM for the treatment of essential tremor and parkinsonian tremor in P150031/S040. The pre-clinical studies provided to support approval in P150031/S001 and P150031/S034 are directly applicable to this PMA because the only requested change is to the indications for use to include bilateral stimulation of the VIM for the treatment of essential tremor, and this change would not affect the non-clinical testing.

### B. Effectiveness Conclusions

In this PMA Supplement, the sponsor provided adequate evidence of the sufficient similarity of the Vercise PC, Vercise Gevia and Vercise Genus DBS Systems to the Abbott Brio Neurostimulation System with regard to its technological characteristics as described in Section IX(B). Therefore, FDA was able to apply Section 216 of the FDAMA and confirm that the evidence presented in the SSED for the Abbott Brio Neurostimulation System approved under P140009, in support of the reasonable assurance of its effectiveness, is directly applicable towards establishing reasonable assurance of the effectiveness of the Vercise PC, Vercise Gevia, and Vercise Genus DBS Systems for bilateral stimulation of the VIM for treatment of essential tremor.

As detailed in the SSED for the Abbott Brio Neurostimulation System, effectiveness for the essential tremor indication was based on 127 patients implanted at 12 U.S. sites. The primary effectiveness endpoint was based on the postural tremor score of the target limb between stimulation On and stimulation Off, at the Day 180 visit, as measured by the blinded reviewer. The primary endpoint was successful, with the stimulation On performing significantly better in their postural or kinetic tremor reduction than stimulation Off at Day 180. In addition, the secondary endpoint of non- target and bilateral side CRST scores showed tremor reduction at Day 180 compared to baseline.

The secondary analyses supported the primary effectiveness endpoint. The CRST which assessed the patients' total motor, handwriting and pouring score demonstrated that stimulation improved all outcomes. In addition, the QUEST and the SF-36 showed improvement.

The results of the clinical study demonstrate a clinically meaningful reduction in tremor with the Brio Neurostimulation System in essential tremor patients with unilateral or bilateral disabling medication-refractory upper extremity tremor.

## C. Safety Conclusions

In this PMA Supplement the sponsor provided adequate evidence of the sufficient similarity of the Vercise PC, Vercise Gevia and Vercise Genus DBS Systems to the Abbott Brio Neurostimulation System with regard to its technological characteristics, as described in Section IX(B). Therefore, FDA was able to apply Section 216 of the FDAMA and confirm that the evidence presented in the SSED for the Abbott Brio Neurostimulation System approved under P140009 is directly applicable towards establishing reasonable assurance of the safety of the Vercise PC, Vercise Gevia and Vercise Genus DBS Systems for bilateral stimulation of the VIM for treatment of essential tremor.

As detailed in the SSED for the Abbott Brio Neurostimulation System, the primary safety endpoint which was a comparison of the rate of device-related or procedure related adverse events within 6 months post-implant compared to a historical control rate of 38.1%. was met. Forty patients (31.5%) had a device or procedure-related adverse event that occurred within 180 days of the initial implant. The one-sided 95% upper confidence bound on this proportion was 38.9%, which is less than 10 percentage points more than the comparator rate of 38.1%.

A total of 34 serious adverse events occurred in 29 patients during the study. These included 8 infections, 3 intracranial hemorrhages, 2 paresis, 1 seizure, 1 stroke and 3 deaths. Two of the 2 deaths were related to cardiac events and the cause of the other death was unknown.

A total of 327 adverse events in 127 (100%) subjects occurred during the study. The most common adverse events were headache, dysarthria, and jolting or shocking sensations. No unanticipated adverse events occurred during the study.

Boston Scientific also performed a multi-center, prospective, double-blind, randomized, controlled study (INTREPID Study) that was design to evaluate the safety and effectiveness of the Vercise DBS System for bilateral stimulation of the STN as an adjunctive therapy for improving dyskinesia and other symptoms in adults with advanced, levodopa-responsive bilateral Parkinson's disease which is not adequately controlled with medication. This study was used to support approval of the Vercise DBS System under P150031. Additional details of this study are provided in the SSED for P150031 that is available on the CDRH website. The Vercise PC, Vercise Gevia and Vercise Genus DBS Systems were approved under P150031/S001 and P150031/S034 based on a similarity of technological characteristics to the Vercise DBS System. Although the data were used to support the safety of DBS at the STN, findings have applicability to the safety of stimulation at the VIM because of similarity of the technological characteristics. Location of the stimulation is different, but stimulation related adverse effects can be resolved at either of the grey matter locations by adjustments to stimulation parameters.

## D. Benefit-Risk Determination

The probable benefits of the Vercise PC, Vercise Gevia, and Vercise Genus DBS Systems are based on data collected in the clinical study conducted to support PMA approval of the Abbott Brio Neurostimulation System. As described above, the sponsor also provided adequate evidence of the sufficient similarity of the Vercise PC, Vercise Gevia and Vercise Genus DBS Systems with regard to its technological characteristics as described in Section

IX(B) such that FDA could apply Section 216 of the FDAMA and cite safety and effectiveness data presented in the SSED for the Abbott Brio Neurostimulation System in support of a determination of reasonable assurance of the effectiveness of the Vercise PC, Vercise Gevia and Vercise Genus DBS Systems for bilateral stimulation of the VIM for treatment of essential tremor.

The probable risks and safety profile of the Vercise PC, Vercise Gevia, and Vercise Genus DBS Systems are the same as for the Abbott Brio Neurostimulation System due to similarity of the technological characteristics.

As documented in the SSED for the Abbott Brio Neurostimulation System, the probable benefits of the device are based on the clinical study. Effectiveness was demonstrated by a reduction in the tremor score. At one year, 86.6% of the patients achieved at least a 2-point reduction in the postural or kinetic tremor scores. It would be expected that subjects with essential tremor who have unilateral or bilateral disabling medication-refractory upper extremity tremor would experience a similar benefit.

The adverse events that were reported were consistent with the safety profile of a legally marketed DBS system.

Limitations:

The study has several limitations. With the exception of the primary effectiveness endpoint, the study assessments were performed in an open label manner. Open label studies may cause an overestimation of the treatment effect in investigator, caregiver and subject ratings. The majority of the patients did not use DBS as an adjunct to medications to control their tremor. However, over time, adjunctive medications may be used which may also confound interpretation of the year data. Missing data from the study could also contribute to the uncertainty. However, this is minimized because overall the study lost/discontinued less than 10% of the total sample. If missing data did occur during the study, in many cases there was backup data collected. For example, if the blinded reviewer was unable to review the data, the investigator also rated the data during the visit, so effectiveness data was able to be captured.

Patient Perspectives:

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

In conclusion, given the available information identified above and its applicability to the Vercise PC, Vercise Gevia, and Vercise Genus DBS Systems, the data support that for bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of disabling upper extremity tremor in adult essential tremor patients whose tremor is not adequately controlled by medications and where the tremor constitutes a significant functional disability, the probable benefits for the Vercise PC, Vercise Gevia and Vercise Genus DBS Systems outweigh its probable risks.

### E. Overall Conclusions

The data in this application and its applicability to the Vercise PC, Vercise Gevia, and Vercise Genus DBS Systems for treatment of essential tremor support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use.

With regard to reasonable assurance of effectiveness of the Vercise PC, Vercise Gevia, and Vercise Genus DBS Systems, the sponsor provided adequate evidence of the sufficient similarity of the Vercise PC, Vercise Gevia, and Vercise Genus DBS Systems and the Abbott Brio Neurostimulation System with regard to technological characteristics. Because of this, FDA was able to apply Section 216 of the FDAMA and confirm that the evidence presented in the SSED for the Abbott Brio Neurostimulation System is directly applicable towards establishing reasonable assurance of the effectiveness of the Vercise PC, Vercise Gevia and Vercise Genus DBS Systems.

With regard to reasonable assurance of the safety of the Vercise PC, Vercise Gevia, and Vercise Genus DBS Systems, the sponsor provided adequate evidence of the sufficient similarity of the Vercise PC, Vercise Gevia, and Vercise Genus DBS Systems and the Abbott Brio Neurostimulation System with regard to technological characteristics. Because of this, FDA was able to apply Section 216 of the FDAMA and confirm that the evidence presented in the SSED for the Abbott Brio Neurostimulation System is directly applicable towards establishing reasonable assurance of the safety of the Vercise PC, Vercise Gevia and Vercise Genus DBS Systems.

## XIII. CDRH DECISION

CDRH issued an approval order on February 29, 2024.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

## XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.

## XV. REFERENCES

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