SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Stimulator, Spinal-Cord, Totally Implanted For Pain Relief

Device Trade Name: Spectra WaveWriter™ SCS System
WaveWriter Alpha™ SCS System
WaveWriter Alpha™ Prime SCS System

Device Procode: LGW, QRB

Applicant's Name and Address: Boston Scientific Corp.
25155 Rye Canyon Loop
Valencia, CA 91355

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P030017/S363

Date of FDA Notice of Approval: February 5, 2023

The original PMA P030017 was approved on April 27, 2004 and is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain. PMA Supplement S275 was subsequently approved on August 11, 2017 to add the following associated conditions and etiologies: radicular pain syndrome, radiculopathies resulting in pain secondary to failed back syndrome or herniated disc, epidural fibrosis, degenerative disc disease (herniated disc pain refractory to conservative and surgical interventions), arachnoiditis, and multiple back surgeries. PMA Supplement S357 was approved on October 5, 2023 to include diabetic peripheral neuropathy (DPN) of the lower extremities for paresthesia-based stimulation. The SSEDs to support these indications are available on the CDRH website and are incorporated by reference here. The current supplement was submitted to expand the indication for the Boston Scientific Spectra WaveWriter, WaveWriter Alpha and WaveWriter Alpha Prime Spinal Cord Stimulator (SCS) Systems to include patients without prior back surgery.

II. INDICATIONS FOR USE

The Boston Scientific Spinal Cord Stimulator (SCS) Systems* are indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following:

- Failed Back Surgery Syndrome,
- Complex Regional Pain Syndrome (CRPS) Types I and II,

- Intractable low back pain and leg pain
- Diabetic peripheral neuropathy of the lower extremities,
- radicular pain syndrome,
- radiculopathies resulting in pain secondary to failed back syndrome or herniated disc,
- epidural fibrosis,
- degenerative disc disease (herniated disc pain refractory to conservative and surgical interventions),
- arachnoiditis,
- multiple back surgeries.

The Boston Scientific Spectra WaveWriter™, WaveWriter Alpha™ and WaveWriter Alpha™ Prime SCS Systems are also indicated as an aid in the management of chronic intractable unilateral or bilateral low back and leg pain without prior back surgery.

*The Boston Scientific Spinal Cord Stimulator (SCS) Systems include the following:

- Precision™ System
- Precision Spectra™ System
- Precision Novi™ System
- Precision Montage™ MRI System
- Spectra WaveWriter™ System
- WaveWriter Alpha™ System
- WaveWriter Alpha™ Prime System

Note: CRPS I was previously referred to as Reflex Sympathetic Dystrophy (RSD) and CRPS II was previously referred to as causalgia.

III. CONTRAINDICATIONS

Patients contraindicated for permanent Spinal Cord Stimulation (SCS) therapy are those who:

- are unable to operate the System
- have failed trial stimulation by failing to receive effective pain relief
- are poor surgical candidates
- are pregnant

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Boston Scientific Spectra WaveWriter, WaveWriter Alpha and WaveWriter Alpha Prime Spinal Cord Stimulator (SCS) Systems labeling.

V. DEVICE DESCRIPTION

The Boston Scientific Spectra WaveWriter, WaveWriter Alpha and WaveWriter Alpha Prime Spinal Cord Stimulator (SCS) Systems are totally implanted devices that deliver electrical stimulation to the dorsal column of the spinal cord for the treatment of chronic intractable pain of the trunk and/or limbs. Figures 1 and 2 display main system components and the typical location of implanted components. Please refer to the Clinician's Manuals for additional information regarding device operation.

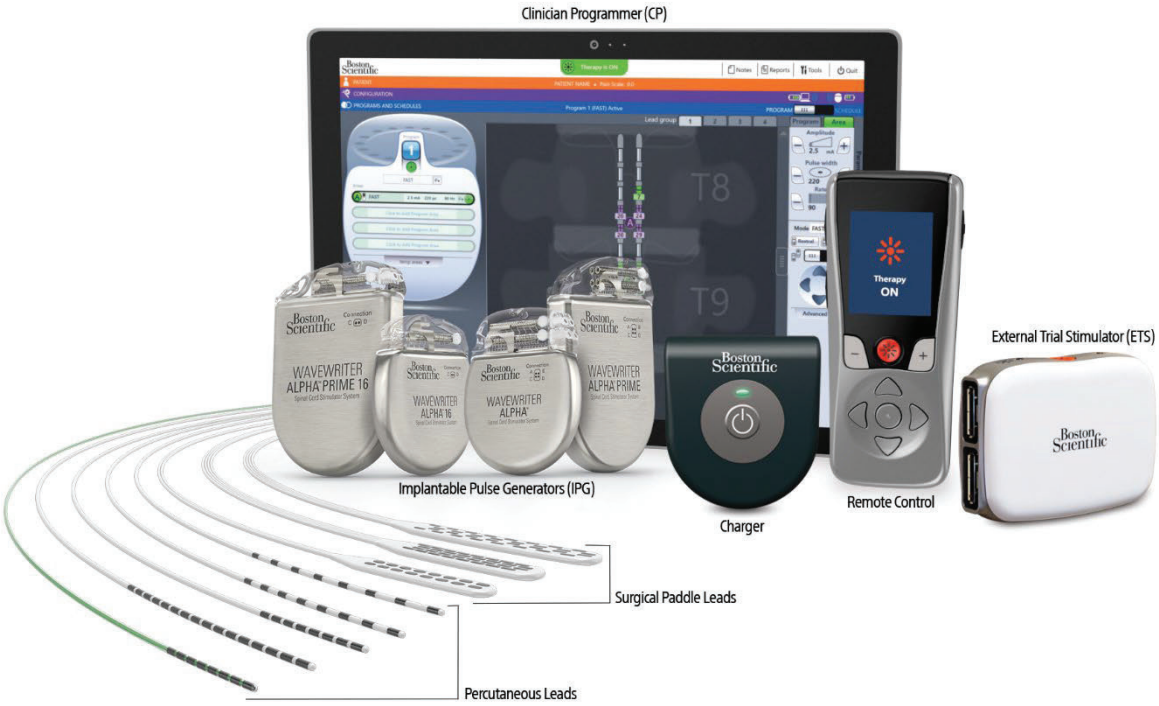

Figure 1: The Boston Scientific WaveWriter SCS Systems

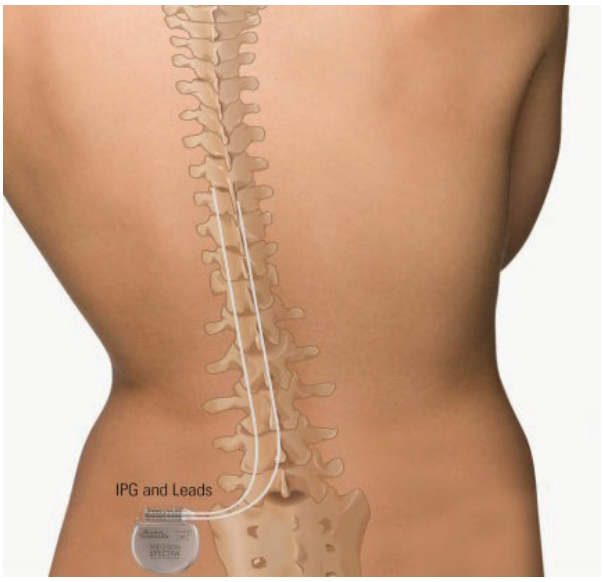

Figure 2: Typical location of implanted pulse generator and percutaneous leads.

A. Implanted Components

The implanted components of the Boston Scientific WaveWriter SCS Systems include the following:

- Implanted Pulse Generator (IPG): The IPG generates programmable electrical pulses that are conducted to the spinal cord via leads. The IPG includes rechargeable or non-rechargeable batteries.
    - IPG models include Spectra WaveWriter, WaveWriter Alpha and WaveWriter Alpha Prime.
- Percutaneous and Surgical Leads: Available in various lengths and configurations, the leads are connected to the IPG to deliver stimulation to the spinal cord.
    - Percutaneous lead models include Linear, Linear ST, Linear 3-4, Linear 3-6, Infinion, Infinion CX and Avista MRI.
    - Surgical lead models include CoverEdge, CoverEdge X and Artisan.
- Lead Extension: Lead Extensions are designed to provide additional length to connect the leads to the stimulator. Lead extensions come in lengths of 25cm, 35cm, and 55cm.

- Lead Splitters: Lead Splitters are optional component used to connect multiple leads to the IPG.

- Implantable Adaptors: Adaptors are provided to connect other manufacturer's leads to Boston Scientific IPGs (e.g., Model M8 adaptor allows IPGs to be connected to Medtronic leads and Model S8 allows IPGs to be connected to Abbott leads).

- Suture Sleeves and Anchors: Suture Sleeves and Anchors are used to anchor the lead to the supraspinous ligament or deep fascia.

B. External Components

The external components of the Boston Scientific SCS System include the following:

- External Trial Stimulator (ETS): The ETS is intended to provide trial stimulation with implanted leads before permanent placement of the IPG. It provides the identical stimulation capabilities as the IPG.

    - ETS models are the Spectra WaveWriter ETS and WaveWriter Alpha ETS.

- Clinician Programmer (CP): The CP installed with the Bionic Navigator programming software is used by the clinician to program the IPG and ETS, and thus prescribe stimulation therapy for the patient.

- Remote Control (RC): 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 the SCS system on and off).

    - RC model is the FreeLink RC.

- Programming Wand: The programming wand is used with some systems to allow the CP to communicate wirelessly with the IPG and ETS.

- Charger: The Charger is used with all rechargeable IPGs to transcutaneously charge the IPG battery.

C. Accessories

Accessories provided with the Boston Scientific SCS Systems include the following:

- Torque Wrench: The wrench is used to tighten the set screws that lock the lead into the IPG.

- Stylets: The stylet is used to maneuver the lead through the epidural space to the desired implant location.
- IPG Template: The IPG Template guides the physician to create the correct sizing of the subcutaneous pocket.
- Insertion Needle: The Insertion Needle is used during implant procedures to introduce the percutaneous lead into the epidural space.
- Lead Blank: The Lead Blank is optionally used during implant procedure to clear a path for the introduction of the lead into the epidural space.
- Tunneling Tool: The Tunneling Tool is used to create a subcutaneous tunnel from the IPG site to the lead implant location.
- IPG Connector Plug/Port Plug: The IPG Connector Plug/Port Plug is provided to seal the port(s) of the IPG that are not in use.
- OR (Operating Room) Cable and Extension: The PR Cable and Extension is used to connect the lead to the ETS during intraoperative testing and trial phase.
- External Adaptors: External Adaptors are used for connecting other manufacturer's SCS leads to the Boston Scientific external stimulators during in-office evaluation.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the treatment of chronic intractable pain of the trunk and/or limbs. Patients are typically treated on a treatment continuum with less invasive therapies prescribed first. Established non-surgical treatment options include, but are not limited to: oral medications (including non-steroidal anti-inflammatory drugs and opioids), massage therapy, physical/occupational/exercise therapy, psychological therapies (e.g., behavior modification, hypnosis), Transcutaneous Electrical Nerve Stimulation (TENS), acupuncture, sympathetic nerve blocks, epidural blocks, intrathecal blocks, and facet joint blocks. The surgical treatment options for these patients include sympathectomy, implantable intrathecal drug delivery systems, partially implanted SCS systems (power source is external), and commercially available fully implantable SCS systems.

Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

Currently, the Boston Scientific WaveWriter SCS Systems are commercially distributed in the United States, European Community (EC) countries, Norway, Switzerland, Great Britain, Canada, Australia/New Zealand, Brazil, Israel, Japan, Argentina, Colombia, Costa Rica, Panama, Belarus, Algeria, Azerbaijan, Georgia, Iraq, Jordan, Kuwait, Kazkhastan, Pakistan, Saudi Arabia, South Africa, Turkey, Ukraine, Singapore and United Arab Emirates.

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

Below is a list of the potential adverse effects (e.g., complications) associated with the use of Spectra WaveWriter, WaveWriter Alpha and WaveWriter Alpha Prime SCS Systems. The Boston Scientific SCS systems are similar to other legally-marketed SCS systems in intended use, target patient population, technology, device design and output characteristics. Therefore, the following list of potential adverse effects have been identified from peer-reviewed published literature that describes studies of all legally-marketed SCS systems.

The adverse effects include: (1) those associated with any surgical procedure, (2) those associated with the SCS system placement procedures, and (3) those associated with having an implanted SCS system to treat pain, including the Boston Scientific SCS System. In addition to the risks listed below, there is the risk that the SCS therapy may not be effective in relieving symptoms, or may cause worsening of symptoms. Additional intervention may be required to correct some of the adverse effects.

- Risks associated with any surgical procedure: abscess; cellulitis; excessive fibrotic tissue; wound dehiscence; wound, local or systemic infection; wound necrosis; edema; inflammation; foreign body reaction; hematoma; seroma; thrombosis; ischemia; embolism; thromboembolism; hemorrhage; thrombophlebitis; adverse reactions to anesthesia; hypertension; pulmonary complications; organ, nerve or muscular damage; gastrointestinal or genitourinary compromise; seizure, convulsion, or changes to mental status; inability to resume activities of daily living; and death.

- Risks associated with SCS system placement procedures: temporary pain at the implant site, infection, cerebrospinal fluid (CSF) leakage, CSF fistula, epidural hemorrhage, bacterial meningitis, seroma, hematoma, and paralysis. Patient use of anticoagulation therapies may increase the risk of procedure-related complications such as hematomas, which could produce paralysis.

- Risks associated with the use of a SCS system: lead migration; IPG migration; allergic response or tissue reaction to the implanted system material; hematoma or seroma at the implant site; skin erosion at the implant site; persistent pain at the IPG, extension, or lead site; radicular chest wall stimulation; disturbed urination;

dysesthesia; decubitus; premature battery depletion; loss of pain relief over time; and uncomfortable stimulation or ineffective pain control caused by random failure of the system components or battery, changes in electrode position, loose electrical connections, lead or extension insulation breaches or fractures; and changes in blood glucose levels.

For the specific adverse events that occurred in the clinical studies, please see Section X below.

IX. SUMMARY OF NONCLINICAL STUDIES

Pre-clinical studies (bench and animal) previously submitted to FDA in the Original PMA application (P030017) and supplements continue to support the safety of the commercially available Boston Scientific WaveWriter SCS Systems for treatment of chronic intractable pain of the trunk and/or limbs. No additional preclinical studies were required to evaluate the safety of Boston Scientific SCS therapy for the treatment of the new patient populations. The previously approved supplements which support the device and its components are listed below:

System/Device Component	Approval Reference
Precision™ Spinal Cord Stimulator System Includes Linear Leads, Lead Extensions, Charger and Base Station	P030017
Artisan Leads	P030017/S008
Linear ST Leads	P030017/S020
Connector M1	P030017/S025
Linear 3-4 and Linear 3-6 Leads	P030017/S100
Infinion Leads	P030017/S119
Infinion CX Leads	P030017/S191
CoverEdge Leads	P030017/S152
M8 Adapter	P030017/S202
S8 Adapter	P030017/S210
Precision™ Montage™ MRI Spinal Cord Stimulator System Includes Avista MRI leads	P030017/S235
Spectra WaveWriter™ Spinal Cord Stimulator System	P030017/S271
Clinician Programmer	P030017/S331
WaveWriter Alpha and WaveWriter Alpha Prime Spinal Cord Stimulator Systems includes IPG, External Trial Stimulator, Remote Control	P030017/S338

X. SUMMARY OF PRIMARY CLINICAL STUDIES

The applicant performed a clinical study in the United States to evaluate the safety and effectiveness of Spinal Cord Stimulation (SCS) with multiple modalities compared to Conventional Medical Management (CMM) in patients with chronic low back and/or leg

pain who have not undergone spinal surgery when using the Boston Scientific WaveWriter SCS Systems. Data from this clinical study were the basis for the FDA approval decision. A summary of the clinical study is presented below

A. Study Design

Patients were treated between March 26, 2021 and May 17, 2023. The database for this Panel Track Supplement reflected data collected through May 17, 2023 and included a ore-specified interim analysis of 60 patients, but the study is currently ongoing. There were 23 investigational sites in the United States.

The SOLIS study was a prospective, multi-center, randomized controlled trial with a parallel group design as shown in the study schematic below. Eligible subjects who passed eligibility criteria were randomized in a 1:1 ratio to receive: spinal cord stimulation (SCS) or conventional medical management (CMM). Subjects with a positive trial proceeded to receive permanent implant, followed by device activation for SCS therapy. Subjects randomized to the CMM group continued with non-surgical, non-invasive treatment (e.g., medication management and interventional pain procedures) for the treatment of their pain. Upon completion of the 3 month visit, subjects in the CMM arm had the option to crossover to receive SCS.

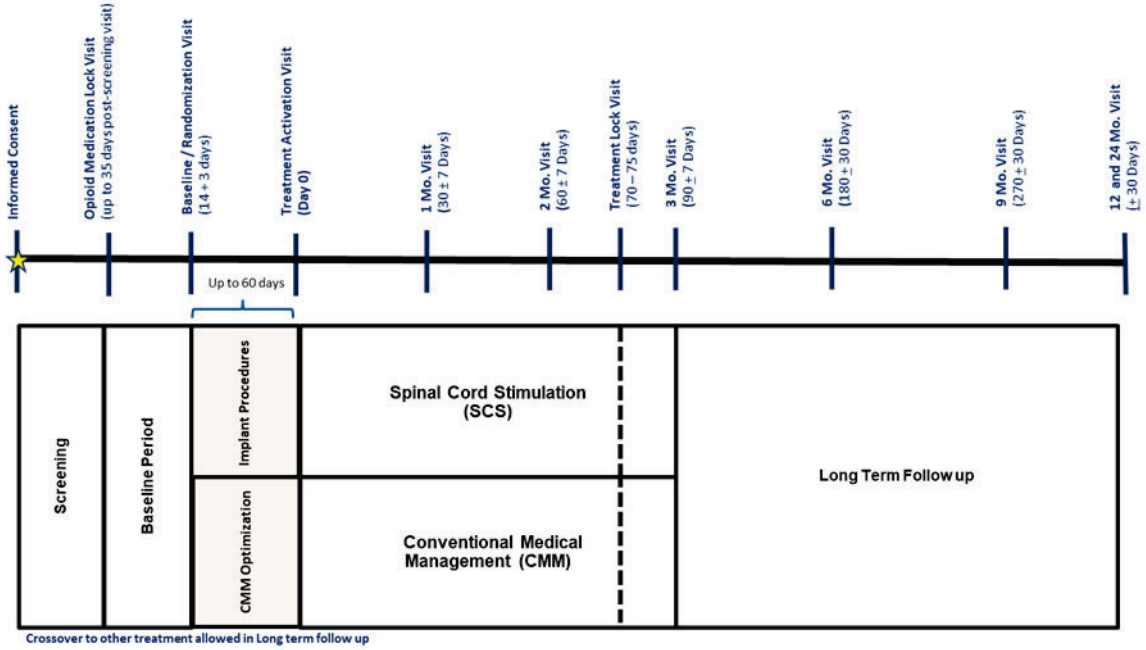

Figure 3: **Schematic of Study Design**

1. Clinical Inclusion and Exclusion Criteria

Subjects were included in the study if they met the following key inclusion criteria:

- Chronic low back pain, with or without leg pain, for at least 6 months with low back pain greater or equal to leg pain.

- Received at least 90 days of documented pain management care to address the primary pain complaint, prior to Screening (e.g. medication, physical therapy).
- 22 years of age or older when written informed consent is obtained.
- If female of childbearing potential: not pregnant, as evidenced by a negative pregnancy test at Screening.
- Subject signed a valid, Institutional Review Board (IRB)-approved informed consent form (ICF) provided in English.

Subjects were considered not eligible for the study if they met the following key exclusion criteria:

- Primary pain complaint of vascular origin (e.g. peripheral vascular disease).
- Require implantation of lead(s) in the cervical epidural space.
- Were part of previous failed spinal cord stimulation trial or are already implanted with an active implantable device(s) (e.g. pacemaker, drug pump, implantable pulse generator).
- Have had previous spinal surgery below the cervical region, where spinal surgery is defined as intradiscal interventions, discectomy, single or multi-level fusion, or decompression procedures (e.g. laminectomy, laminotomy, foraminotomy).

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 3-, 6-, 9-, and 12-months postoperatively.

Preoperatively, patients were screened for inclusion/exclusion criteria and baseline assessments were taken prior to randomization and implantation. Postoperatively, the objective parameters listed in section 3 below were measured during the study. Adverse events and complications were recorded at all visits.

The key timepoints are shown above in Table 3 above summarizing the study design.

3. Clinical Endpoints

With regards to safety, rates of occurrence of adverse events and device events were recorded, specifically as follows:

- Non-related, non-serious adverse events from the time of consent up to 3 months post-activation
- All device hardware, device stimulation and/or procedure related non-serious adverse events, all serious adverse events, and unanticipated adverse events through the end of the study

With regards to effectiveness, the primary endpoint was the proportion of subjects with 50% or greater reduction from baseline in average overall (low back and/or leg pain) intensity at 3 months post-activation with no increase in baseline average daily opioid medications used to treat pain, compared between SCS and CMM, evaluated

using the Percent Pain Relief (PPR) scale. The following secondary endpoints were also assessed throughout the study:

- Change in overall (low back and/or leg) pain intensity from Baseline Visit to 3 months post-Activation Visit (VRS)
- Change in low back pain intensity from Baseline Visit to 3 months post-Activation Visit (VRS)
- Change in leg pain intensity from Baseline Visit to 3 months post-Activation visit (VRS)
- Percent Pain Relief in overall (low back and/or leg) pain at 3 months post-Activation Visit (PPR)
- Percent Pain Relief in low back pain at 3 months post-Activation Visit (PPR)
- Percent Pain Relief in leg pain at 3 months post-Activation Visit (PPR)
- Patient global impression of change at 3 months post-Activation Visit (PGI-C)
- Clinician global impression of change at 3 months post-Activation Visit (CGI-C)
- Treatment Satisfaction at 3 months post-Activation Visit (TSQM-9m)
- Change in disability from Baseline Visit to 3 months post-Activation Visit (ODIv2.1a)
- Change in sleep from Baseline Visit to 3 months post-Activation Visit (PSQI)

With regard to success/failure criteria, patients will be considered treatment responders if they experience a 50% or greater improvement in their overall pain. The study will be considered a success if the if the lower bound of the two-sided 95% confidence interval for the difference between treatment and control groups is great than 0 using the Intent-To-Treat (ITT) analysis set.

B. Accountability of PMA Supplement Cohort

The results are based on the data snapshot taken as of September 14, 2022, defined by the pre-specified interim analysis interval. At the time, a total of 212 subjects had provided informed consent and were enrolled in the study. Figure 4 below outlines the subject disposition in the study as of the data snapshot. Given the ongoing nature of the study, several visits were still pending as subjects have not reached their visits as required by study protocol.

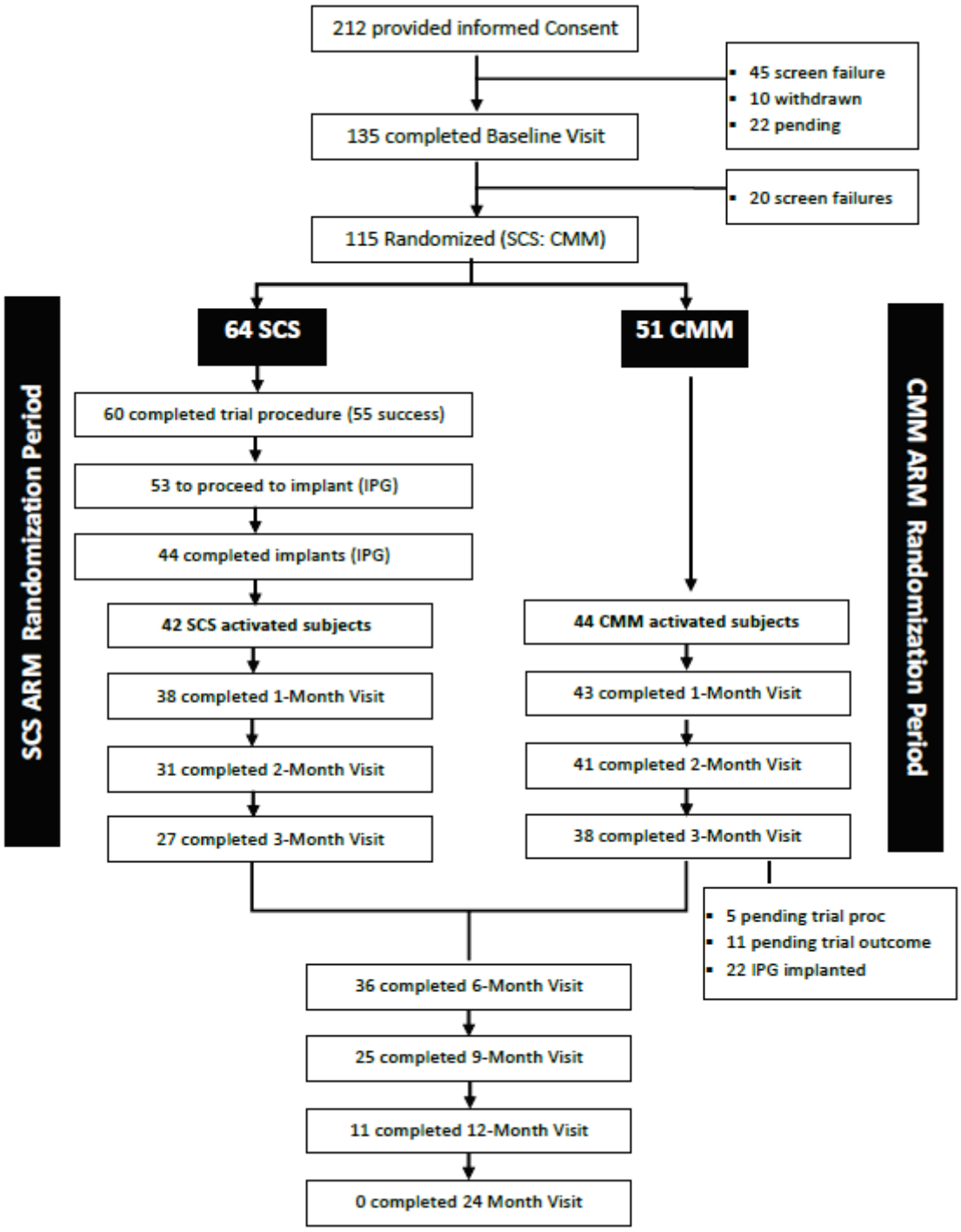

Figure 4: Subject Disposition

Of the 212 enrolled subjects, 135 subjects completed their Baseline Visit. 45 subjects were screen failures, 10 withdrew participation and 22 were still pending Baseline Visit at the time of the snapshot. Of the 135 subjects that completed their Baseline Visit, 20 more subjects were deemed as screen failures resulting in 115 subjects randomized (64 SCS, 51 CMM).

At the time of snapshot, 60 of 64 subjects randomized to SCS completed their trial procedure and 55 (91.6%) reported a successful trial with 50% or more improvement in their overall pain at end of trial. Fifty-three subjects decided to proceed to receive IPG and 44 completed their procedure at the time of snapshot. Forty-two subjects in the SCS group and 44 in the CMM group completed their treatment activation visit and subsequently completed study follow up as shown in figure above.

A total of 11 subjects completed their 1-year visit and 1 subject reached their 2-year visit as of September 14, 2022.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for an SCS study performed in the US. The proportions of enrolled subjects are also consistent with the age, sex/gender, racial and ethnic prevalence of the chronic pain condition.

The baseline demographics and clinical characteristics of the 60 treatment activated subjects are summarized in tables below. The mean age of subjects was 59.8 ± 11.2 years and 56.7% (34/60) were females. Ninety three percent were Caucasian.

Table 1: Baseline Demographic Characteristics

Category	
Age (years) Mean (SD) n Median, (Min, Max) 95% CI	 59.8 (11.2) 60 60.5 (37.0, 81.0) [56.9, 62.7]
Gender	
Male % (n/N)	43.3% (26/60)
Female % (n/N)	56.7% (34/60)
Race and Ethnicity	
Of African heritage	6.7% (4/60)
Caucasian	93.3% (56/60)

A summary of subjects' clinical characteristics is provided in the table below. At the time of enrollment, study subjects reported an overall pain (low back and/or leg) of 7.6 ± 0.8 (n = 60) based on scale of 0-10 where 0 is no pain and 10 is the worst pain possible. Subjects reported mean low back and leg pain of 7.7 ± 0.8 (n = 60) and 5.9 ±

1.4 (n = 43) scores respectively. As noted from their pain scores, these subjects had severe pain at study start. Subjects reported low back pain for 15.4 ± 12.3 years. Study subjects were also severely disabled based on their mean summary score of 56.2 ± 9.2 (n = 60) as measured on the Oswestry Disability Index (ODI).

Table 2: Baseline Clinical Characteristics

Category	Mean (SD) n Median, (Min, Max) 95% CI
Average overall pain (VRS)	7.6 (0.8) 60 8.0 (6.0, 10.0) [7.3, 7.8]
Average low back pain (VRS)	7.7 (0.8) 60 8.0 (6.0, 10.0) [7.5, 7.9]
Average leg pain (VRS)	5.9 (1.4) 43 6.0 (1.0, 8.0) [5.5, 6.3]
Duration of Low Back Pain (years)	15.4 (12.3) 60 13.0 (1.0, 54.0) [12.2, 18.6]
Oswestry Disability Index (ODI) Summary Score	56.2 (9.2) 60 55.6 (40.0, 77.8) [53.9, 58.6]

D. Safety and Effectiveness Results

1. Safety Results

As of September 14, 2022, a total of 116 adverse events were reported among 48 subjects across the entire study population (all 212 consented subjects). Adverse event relationships were assessed and reported by the investigators and the site-reported adverse event terms were coded using the Medical Dictionary for Regulatory Activities (MedDRA).

Of the 116 adverse events, 25 were serious adverse events (SAEs) and 91 were non-serious adverse events. Of the 25 SAEs (13 subjects), 19 events were considered to be unrelated to SCS or CMM. The SAEs found related to the study or procedure include rhabdomyolysis, cellulitis, systemic infection, epidural abscess, cauda equina syndrome, and paraspinal abscess. Since the snapshot, the relatedness for the one CMM subject was determined to be unrelated due to entry error. Of the remaining related serious events for the SCS cohort, they were all attributed to one subject.

Of the 91 non-serious events, 58 were unrelated to procedure, hardware/device and/or stimulation. The most related common events included dermatitis contact (2 events),

nausea (3 events) and paresthesia (2). Other events include nausea, dysphagia, post lumbar puncture syndrome, muscle spasms, pain in extremity, coccydyria, cellulitis, postoperative wound infection, systematic infection, implant site erythema, implant sire extravasation, implant site pain, medical device discomfort, hematoma, and device stimulation issue,

Device issues reported during the study include IPG set screw improperly inserted, lead breakage, remote control communication issues, lead migration, and high lead impedance. No instance of device malfunction was related to adverse events.

One death was reported in the study due to chronic obstructive pulmonary disease (COPD), which was reported as not related to procedure, device or stimulation. There were no unanticipated adverse events in the study.

2. Effectiveness Results

The following primary endpoint results are based on the successful completion of interim analysis for effectiveness.

The primary endpoint of the study was the proportion of subjects with 50% or greater reduction from baseline in average overall (low back and/or leg pain) intensity at 3 months post-activation with no increase in baseline average daily opioid medications used to treat pain, compared between SCS and CMM.

The study successfully met its primary endpoint based on a pre-specified cohort of 60 treatment activated subjects at 3 months ($p < 0.0001$). An 87.5% (21/24) responder rate with no increase in opioids was reported in the SCS group compared with 8.3% (3/36) in the CMM group (ITT group) [79.2% difference between the groups, $p< 0.0001$]. Thus, SCS demonstrated superiority in outcomes as compared with CMM in patients with no prior surgery based on ITT group. These results are shown in the graph below.

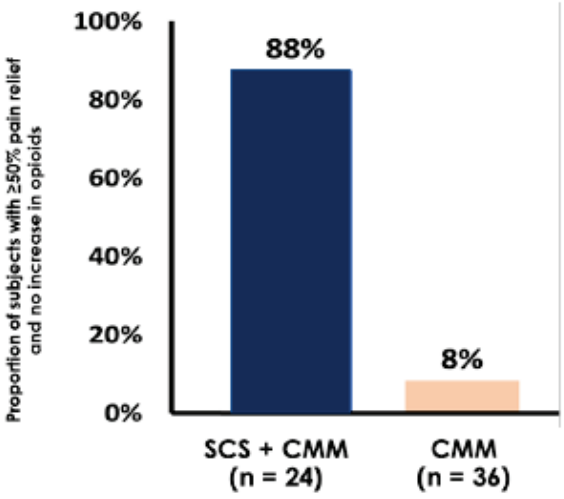

Figure 5: Primary Endpoint Results Of the 60 subjects in the ITT group, 6 subjects had major protocol deviations due to an increase in their opioid medications during the randomized phase and were excluded from per-protocol analysis (n = 54). All 6

subjects were in the CMM group. The study also met its primary endpoint in the per-protocol population (n = 54) supporting the robustness of the study with a 77.5% difference between the groups ($p < 0.0001$, 87.5% in SCS group, 10.0% in CMM group).

The applicant also submitted additional data that documented sustained results at 6-month and 12-month follow-up intervals, consistent with the positive outcomes reported at the primary endpoint interval. The table below shows the results for overall pain relief at 6-, 9-, and 12-months measured using the PPR scale. Please note that the lack of difference between groups at 9- and 12-months is due to the ability of patients in the control group to cross over to the treatment group at 6-months. Most control group patients were receiving SCS therapy at the 9- and 12-month timepoints.

Table 3: Percent Pain Relief (PPR) of Overall Pain at 6-, 9-, and 12-months for the ITT population

	Overall Pain (PPR) (%)		
From 0-100%, what percentage of your overall pain (low back and/or legs) has been relieved by study treatment since baseline?	Intent-To-Treat Subjects Treatment Activated (N = 128) Mean (SD) N Median (Min, Max) [95% CI]	Randomized to Spinal Cord Stimulation SCS Treatment Activated (N = 63) Mean (SD) N Median (Min, Max) [95% CI]	Randomized to Conventional Medical Management CMM Treatment Activated (N = 65) Mean (SD) N Median (Min, Max) [95% CI]
6 months post activation	64.0 (31.6) 85 76.0 (0.0, 100.0) [57.2, 70.8]	72.1 (23.0) 46 76.0 (0.0, 100.0) [65.3, 78.9]	54.5 (37.6) 39 71.0 (0.0, 100.0) [42.3, 66.7]
9 months post activation	69.6 (27.2) 70 80.0 (0.0, 100.0) [63.1, 76.1]	69.7 (26.2) 37 79.0 (7.0, 100.0) [61.0, 78.4]	69.4 (28.8) 33 80.0 (0.0, 100.0) [59.2, 79.6]
12 months post activation	79.2 (17.8) 51 83.0 (31.0, 100.0) [74.2, 84.2]	77.0 (20.0) 23 80.0 (31.0, 100.0) [68.3, 85.6]	81.1 (15.9) 28 84.0 (42.0, 100.0) [74.9, 87.3]

3. Pediatric Extrapolation

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

XI. 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 included 23 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 b
- y 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. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data.

XII. 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 supplement 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.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The SOLIS study was designed to evaluate the safety and effectiveness of Spinal Cord Stimulation (SCS) in patients with chronic low back and/or leg pain who have not undergone spinal surgery when using the Boston Scientific WaveWriter SCS Systems.

The study is a prospective, multicenter, parallel group randomized controlled trial with an adaptive design where subjects were randomized to either receive SCS or CMM for up to 3 months post-activation. The primary endpoint of the study was the proportion of subjects with 50% or greater reduction from the Baseline in average overall (low back and/or leg) pain intensity at 3 months post-activation, with no increase in baseline average daily opioid medications used to treat pain, compared between SCS and CMM.

A total of 212 patients provided informed consent to participate in the study as of September 14, 2022. Of these 212 subjects, 115 subjects were randomized, and 86 subjects reached their treatment activation visit (42 SCS, 44 CMM). Subjects continued in the study following completion of their 3-month follow up as described in the study protocol up to 2 years. The pre-specified interim analysis reported the effectiveness of 60 activated subjects that completed their 3 Month post-activation visit.

Subjects with a mean (SD) age of 59.8 ± 11.2 years (56.7% females) reported an overall (low back/leg) pain of 7.6 ± 0.8 at study start (n = 60). Subjects reported similar scores for low back pain (7.7 ± 0.8) as well. Pain scores were reported by subjects on a scale of 0 – 10 where 0 was no pain and 10 was worst pain possible. As noted from their reported pain scores, these subjects had severe pain at study start. Additionally, these subjects were also severely disabled based on their mean summary score of 56.2 ± 9.2 (n = 60) as measured on the Oswestry Disability Index (ODI).

The study successfully met its primary endpoint based on a prespecified cohort of 60 activated subjects where SCS demonstrated superior outcomes with an 87.5% responder rate with no increase in opioid medications compared with 8.3% in the CMM group ($p < 0.0001$) at 3 months post-activation.

The additional data that documented sustained results at 6-month and 12-month follow-up intervals was consistent with the positive outcomes reported at the primary endpoint interval.

B. Safety Conclusions

At the time of the interim analysis snapshot, a total of 116 adverse events were reported among 48 subjects across the entire study experience (all 212 consented subjects). Of the 116 adverse events, 25 were serious adverse events (SAEs) and 91 were non-serious adverse events. Among 25 SAEs, majority of them (19 of 25) were considered unrelated to SCS or CMM. Of the remaining related serious events for the SCS cohort, they were all attributed to one subject. One death was reported in the study due to chronic obstructive pulmonary disease (COPD). This was reported as not related to procedure, device or stimulation. There were no unanticipated adverse events. None of the reported device deficiencies were related to adverse events.

C. Benefit-Risk Determination

The SOLIS study met its primary effectiveness endpoint with statistical significance in that the SCS group experienced a greater percentage of pain relief compared to the CMM group. Despite the uncontrolled study design, the results demonstrate effectiveness of SCS therapy in patients without prior back surgery. The study successfully met its primary endpoint based on a prespecified cohort of 60 activated subjects where SCS demonstrated superior outcomes with an 87.5% responder rate with no increase in opioid medications compared with 8.3% in the CMM group ($p < 0.0001$) at 3 months post-activation. In terms of risk, out of the 116 adverse events reported, 25 were serious adverse events (SAEs) and 91 were non-serious adverse events. Among 25 SAEs, majority of them (19 of 25) were considered unrelated to SCS or CMM. The 6 events related to the study were attributed to one patient and results from an epidural abscess along with subsequent complications. Additionally, the non-serious adverse events are commonly associated with SCS therapy and spine surgery which do not raise concern. Therefore, we can conclude that the benefits outweigh the risks.

1. Patient Perspectives

   This submission either did not include specific information on patient perspectives or the information did not serve as part of the basis of the decision to approve or deny the PMA for this device.

In conclusion, given the available information above, the data support that for Spectra WaveWriter SCS System, WaveWriter Alpha SCS System, and WaveWriter Alpha Prime SCS System the probable benefits outweigh the probable risks.

D. Overall Conclusions

The data in this PMA supplement support the reasonable assurance of safety and effectiveness for the WaveWriter SCS Systems (i.e., Spectra WaveWriter SCS System, WaveWriter Alpha SCS System, and WaveWriter Alpha Prime SCS System) when used in accordance with the indications for use. The SOLIS study successfully met its primary endpoint based on a prespecified cohort of 60 activated subjects where SCS demonstrated superior outcomes with an 87.5% responder rate with no increase in opioid medications compared with 8.3% in the CMM group ($p < 0.0001$) at 3 months post-activation. Adverse event rates tracked during the study also provide an assurance of safety, since the rate and type of events are what we would expect for use of SCS therapy for already approved indications.

XIV. CDRH DECISION

CDRH issued an approval order on February 5, 2023.
The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XV. 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.