



MEMORANDUM

SUMMARY OF:

P910077/S139
P960040/S306
P010012/S341
DYNAGEN, INOGEN, and ORIGEN CRT-D and ICD devices
Model 2868 Application Software, v3.03
Model 3120 ZOOM LATITUDE Programming System
-Model 2909 System Software (MAU) v9.02
-Model 3140 ZOOM Wireless Transmitter
-Model 3141 USB Cable

Boston Scientific

BACKGROUND

Boston Scientific Corporation has developed new pulse generator models based on the software and hardware architectural platform used to develop its predecessor devices, INCEPTA, ENERGEN, and PUNCTUA (P010012/S255 and P960040/S235, approved November 17, 2011).

New pulse generator models will be marketed under the names DYNAGEN CRT-D, INOGEN CRT-D, ORIGEN CRT-D, DYNAGEN ICD, INOGEN ICD and ORIGEN ICD. The new pulse generators will take the place of PROGENY devices in BSC CRM's CRT-D and ICD offerings. Modifications to the INCEPTA, ENERGEN, and PUNCTUA baseline, to develop these new models, include:

- Changing wireless RF telemetry communication frequency to MICS (Medical Implant Communication Service)
- Adding LV IS4 header type to enable the capability in new devices to deliver pacing pulses to and sensing from each of the four LV electrodes when the device is connected with an LV lead with four electrodes
- Implementing design enhancements to the electrical and mechanical hardware
- Updating the header manufacturing process to the (b)(4) Trade Secret/CCl process
- Updating software to incorporate performance and customer satisfaction enhancements
- Updating labeling to reflect new models and new features, as well as incorporate additional information for clarity and customer ease of use

The Model 2868 Programmer Application Software (2868 PRM SW), currently used to communicate with the COGNIS/TELIGEN (P010012/S165 and P960040/S155, approved May 8, 2008) and INCEPTA/ENERGEN/PUNCTUA devices, will be modified to support the DYNAGEN, INOGEN, ORIGEN devices. The modified 2868 PRM SW will continue to communicate with the marketed released COGNIS/TELIGEN and INCEPTA/ENERGEN/PUNCTUA devices. Therefore Boston Scientific is also requesting approval to add enhancements typical of software maintenance for COGNIS/TELIGEN and INCEPTA/ENERGEN/PUNCTUA devices. There are no changes to the hardware or PG firmware used in COGNIS/TELIGEN or INCEPTA/ENERGEN/PUNCTUA devices.

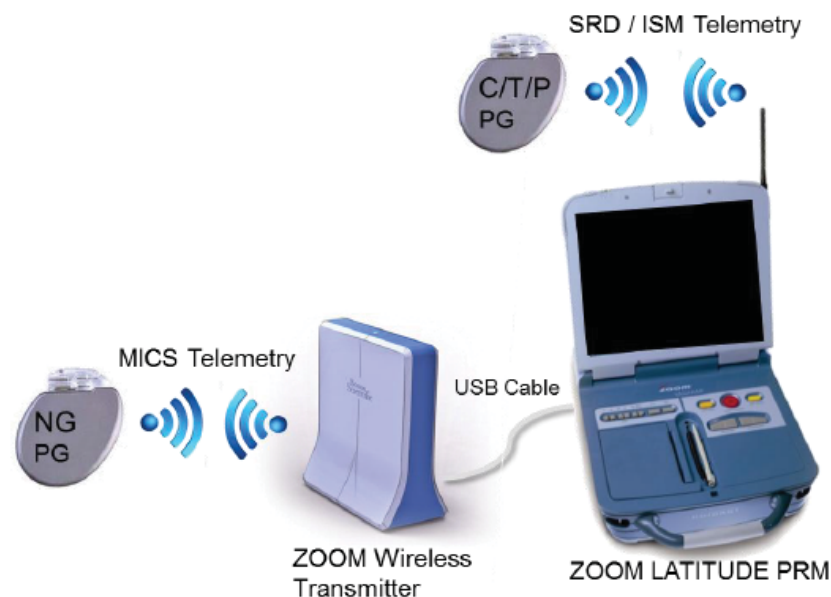
Boston Scientific has developed a new radio frequency (RF) antenna accessory, the Model 3140 ZOOM Wireless Transmitter (ZWT). The ZWT will be used with the currently approved Model 3120 ZOOM LATITUDE Programmer (PRM) to support the interrogation and programming of a newly developed family of pulse generator (PG) devices. These PGs are Boston Scientific's Next Generation tachy devices (NG family) for Cardiac Resynchronization Therapy - Defibrillator (CRT-D) and Implantable Cardioverter Defibrillator (ICD) devices. These PGs were submitted as PMA supplements to P010012 (for CRT-Ds) and P960040 (for ICDs), and are currently under FDA review.

Currently, the PRM supports RF telemetry in the ISM (902 – 928 MHz) frequency band for predecessor Boston Scientific PGs. The ZWT was developed to allow the PRM to interrogate and program Boston Scientific's new NG family of PGs using RF telemetry in the Medical Implant Communication Service (MICS) (402 – 405MHz) frequency band.

This submission requests approval for the Model 3140 ZWT and the associated modifications to the Model 3120 PRM software necessary to support the use of MICS RF telemetry.

Originally the Model 3140 ZWT and the Model 3120 PRM software were submitted as a separate PMA/s. However, a decision was made to change the submission to **Amendment A001** since the Model 2909 System Software which is part of the Model 3120 PRM software is necessary to communicate with the new family of ICDs and CRT-Ds.

Figure 1-1: System Illustration of RF Telemetry



BSC provided a presentation which provided an overview of the submission.

BSC has submitted a few applications that are relevant to BSC's new NG and ZWT devices to FDA. These applications are: NG sPMAs P010012/S341 & P960040/S306, ZWT sPMA P910077/S139/A001, ACUITY X4 IDE G130222 and CAPTIVATE IDE G130241. As many exhibits included in these applications are the same, BSC put together a summary that provided a quick reference of the shared exhibits in different applications.

In **Amendment A002**, the sponsor provided a response to the seven deficiencies which resulted from review of the original submission and **Amendment A001**.

INDICATIONS FOR USE

No changes are requested to ICD and CRT-D indications. There is also no change to PRM intended use.

DEVICE DESCRIPTION AND CHANGE DESCRIPTION

The new NG pulse generators are based upon the INCEPTA/ENERGEN/PUNCTUA pulse generators. Changes from the predecessor devices to create the new devices are described in the following subsections; the changes include modifications to the hardware (Section 2.1), 2868 PRM software and PG firmware (Section 2.2.3). Some of the changes result in new or modified features which are described Section 2.3.1.

A limited number of proposed changes also impact INCEPTA/ENERGEN/PUNCTUA and COGNIS/TELIGEN pulse generators through the modification of the 2868 PRM software update.

Table 2-1 in the main document of the original submission describes the mechanical and electrical changes that will be implemented in NG devices, relative to the predecessor. A high level listing of the changes is provided below:

(b)(4) Trade Secret/CCI



A summary of changes to the 3120 PRM is provided in Section 2.1 of the main document in **Amendment A001**. This includes the addition of the ZWT external antenna accessory and PRM software changes to support MICS RF telemetry.

A detailed description of the ZWT antenna accessory functional components and characteristics is described in Section 2.2 of the main document in **Amendment A001**. This includes a description of external and internal assembly, principles of operation, device functionality, safety features, technical specifications, performance standards, packaging, and major component suppliers.

Currently, the PRM supports RF telemetry in the ISM (902 – 928 MHz) frequency band for predecessor Boston Scientific PGs. The ZWT was developed to allow the PRM to interrogate and program Boston Scientific's new NG (Next Generation tachy devices) family of PGs using RF telemetry in the Medical Implant Communication Service (MICS) frequency band (402 – 405 MHz). The ZWT connects to the PRM via the Model 3141 USB Cable. The ZWT provides the required hardware and software to communicate wirelessly with certain BSC PGs using MICS RF telemetry.

A comparison of the existing PRM and the proposed PRM and ZWT configuration (subject of this submission) is outlined in Table 2-1 of the main document in **Amendment A001**. Changes

to the PRM are limited to the addition of the ZWT external antenna accessory and PRM software changes. No internal hardware or electronics changes have been made to the PRM. No changes were made to the PRM Intended Use or Contraindications.

The ZWT has been developed as an external antenna accessory to the PRM in order to support wireless MICS telemetry with BSC NG PGs. MICS is a bidirectional radio frequency (RF) communication standard for medical devices that uses a frequency band between 402 and 405 MHz. Boston Scientific is making this change to the RF frequency band because the MICS band is accepted globally, minimizing the differences between the device systems manufactured for distribution in different geographies. Additionally, the MICS frequency band is dedicated to medical devices, which limits potential interferers to medical devices.

The MICS communication frequency band is split into 10 “channels” that allow multiple RF device telemetry communication sessions to coexist within the frequency band. When a MICS band device encounters interference on the current communication channel, the MICS protocol defines methods to establish communication using one of the available channels. Previous Boston Scientific devices did not have this flexibility and were prohibited from using wireless RF telemetry communication if the communication channel was already in use by another device. This is because the previous telemetry protocol employed one channel within the frequency band.

Inductive telemetry (wanded) communication is not affected by the change in wireless RF frequency band and remains as an alternate to wireless RF telemetry communication.

The ZOOM LATITUDE Programming System includes software programs that execute on the PRM and the ZWT. The PRM software application used to interrogate and program NG PGs is the Model 2868 Programmer Application Software. This software application is started by the Multiple Application Utility (MAU) software application via user menu selection or a PG auto-identification feature called (b)(4) Trade Secret/CCI. The 2868 Programmer Application Software exchanges data with the PG using PRM operating system software (software radio/MICS device driver/common protocols) and the ZWT external antenna accessory for MICS RF telemetry. Telemetry continues to be supported for BSC’s ISM/SRD band PGs and there are no changes to this functionality. Inductive telemetry (wanded, non-RF) continues to be supported for all BSC PGs and there are no changes to this functionality.

RISK ANALYSIS

To ensure that Boston Scientific provides acceptably safe products to the marketplace, a formal safety risk management process is in place that facilitates risk analysis, evaluation, and control. Safety risk management is performed throughout the product life cycle.

Safety risk analysis, evaluation, and control activities are specified in the Safety Risk Management Plan. The Safety Risk Management Report contains a confirmation that the safety risk management process has been performed according to Boston Scientific policies and procedures, that the hazards associated with the designed system have been identified, and that the risks have been mitigated to an acceptable level. The report also confirms that Boston Scientific believes that the overall residual safety risk associated with the use of the system is acceptable, and that the system is acceptable for use in humans.

The risk management activities that were completed for this submission are summarized in Table 5-6 in the original submission and detailed in the original submission. They are also listed below:

- Hazard Analysis

- Exhibit 5-52: PG Hazard Analysis Report (b)(4) Trade Secret/CCI
 - Exhibit 5-53: PG Safety Information Verification Report (b)(4) Trade Secret/CCI
- Security Risk Assessment Report
 - Exhibit 5-54: Security Risk Assessment (b)(4) Trade Secret/CCI
- Reliability Prediction Analysis
 - Exhibit 5-55: NG3 Reliability Prediction (b)(4) Trade Secret/CCI
- Safety Risk Management Report
 - Exhibit 5-56: PG Safety Risk Management Report (b)(4) Trade Secret/CCI

The risk management activities that were completed for the ZWT are both summarized in Table 5-4 and detailed in **Amendment A001**. They are also listed below:

- Hazard Analysis
 - Exhibit 5-22: PRM Hazard Analysis Report (b)(4) Trade Secret/CCI
 - Exhibit 5-23: PRM Safety Information Verification Report (b)(4) Trade Secret/CCI
- Security Risk Assessment Report
 - Exhibit 5-24: Security Risk Assessment (b)(4) Trade Secret/CCI
- Reliability Prediction Analysis
 - Exhibit 5-25: Gamera Reliability Prediction (b)(4) Trade Secret/CCI
- Safety Risk Management Report
 - Exhibit 5-26: PRM Safety Risk Management Report (b)(4) Trade Secret/CCI

Reviewer Comment: I reviewed the Hazard Analysis and reports identified above. It appears that the sponsor has completed the appropriate analysis by identifying the hazards and evaluating the residual risk of the hazards. There are no further concerns.

CLINICAL

The Clinical reviewer provided the clinical review. The following sections of the original submission were reviewed:

- Description of SW changes – section 2.2.3 (review change list for any clinical concerns)
- Simulated Use Testing – Section 5.2.2, Exhibit 5-10
- Tape Testing – section 5.2.4, Exhibits 5-13 and 5-14
- Clinical Study – section 6
- IFU and Labeling – section 9

A clinical review of the information in **Amendment A001** was deemed not necessary since there was no clinical impact of the ZWT and PRM changes.

He found the testing submitted support appropriate function of the devices and no changes made have altered the benefit-risk analysis. The associated IFUs and labeling are appropriate. He had no specific clinical concerns.

Regarding the addition of the NG quadripolar CRT-D PG with an IS-4 header, BSC did submit a presubmission (Q120409 – Exhibit 6-3 in the original submission) to gain FDA concurrence and feedback on the evaluation plan and labeling for market approval prior to the availability of a BSC quadripolar LV lead. The FDA feedback stated:

- a head-to-head study with several different market-approved IS4 leads would not be required if BSC labels the header as compatible only with the St. Jude Quartet
- if the animals in the GLP are not sacrificed, FDA concurred that lead-tissue interface evaluation was not required

BSC conducted a GLP study with St. Jude Quartet leads. The animal study was reviewed by the Animal Testing reviewer and is discussed in that part of the memo. BSC updated their labeling to include compatibility specifically with the St. Jude lead as detailed in section 9 of the submission. The original labeling regarding the compatibility with the St. Jude lead is in Exhibit 9-2: Physician Technical Manual CRT-D of the submission. However, after further discussion and a request by FDA the labeling was modified to state that compatibility with the St. Jude Quartet IS4 lead has been demonstrated through chronic in-vivo animal GLP testing.

NON-CLINICAL LABORATORY STUDIES (ORIGINAL SUBMISSION)

System Evaluation Plan/Report

A System Evaluation Plan is created and maintained throughout the project to define the specific types of evaluation that are appropriate for a given product under development. Techniques used for evaluation include design validation, design verification, design analysis, manufacturing process validation, and safety and security risk management. The System Evaluation Plan completed for the NG devices and ZWT:

- describes all verification and validation activities performed for the system to ensure that the system is properly evaluated prior to first human use and market release
- indicates the relationships between requirements documents, with a map to the work products of the test groups responsible for developing tests from these requirements documents

The System Evaluation Report summarizes the testing and results of the non-clinical design validation and design verification activities, as well as the safety and security risk management activities, identified in the System Evaluation Plan. The System Evaluation Report (SER) completed for the NG device and ZWT:

- provides a comprehensive view of the evaluations performed for the system
- focuses on the acceptable system performance of the product being submitted
- delineates what is new and what is modified in the system being evaluated
- provides traceability to documented rationale for decisions made regarding testing
- provides the clinical perspective of the impact of any anomalies known in the system
- covers testing performed as part of the formal evaluation of the product
- ensures the specific evaluations performed for the system were appropriate and complete

The System Evaluation Plan NG (b)(4) Trade Secret/CC is provided as Exhibit 5-1.

The System Evaluation Report NG (b)(4) Trade Secret/CC is provided as Exhibit 5-2.

Reviewer Comment: The System Evaluation Report and Plan were reviewed and found acceptable. The sponsor appears to have successfully completed the testing.

Ripple Effects Analysis and Test Roadmaps

Ripple effects analysis (REA) is the process for identifying which parts of the device/system are affected by the changes. When performing an REA, the impact of the change is analyzed to determine the effect on the system and the recommended testing to be performed to verify the change.

There were three (3) REAs created for this project. Changes were evaluated on a case by case basis to determine if additional testing was necessary to verify that the device continued to meet design requirements after the change. These REAs document the details of the changes (e.g.

design specifications, materials, software changes, etc.) and analyze the changes for ripple into the rest of the design. Based on the analysis, the REA recommended additional testing to verify the impact of some of the changes. Test Roadmap was created for each REA to provide a “walk-through” of all testing required per the REA.

The REAs and test roadmaps are provided as follows:

- Exhibit 5-3: System REA ((b)(4) Trade Secret/CCI [REDACTED])
- Exhibit 5-4: System REA Test Roadmap: ((b)(4) Trade Secret/CCI [REDACTED])
- Exhibit 5-5: Hardware REA ((b)(4) Trade Secret/CCI [REDACTED])
- Exhibit 5-6: Capacitor REA ((b)(4) Trade Secret/CCI) ((b)(4) Trade Secret/CCI [REDACTED])

Reviewer Comment: The REA and Test Roadmap documents were reviewed and found acceptable. The sponsor appears to have done the appropriate analysis to determine which testing is required for the changes.

Design Validation Testing

System Features Testing

System Features testing is one part of a comprehensive system evaluation plan and consists of design validation test cases that demonstrate that the system meets the users’ needs and intended uses. The System Features Testing focuses on the overall integration of the system elements using a simulated environment, rather than the detailed function of the individual devices. Individual tests demonstrate the functionality of a given feature or system behavior, rather than provide exhaustive testing of possible scenarios.

The system features test used the following test articles:

- NG3 PG with Firmware Version E_v1.02
- Model 2868 Programmer Application SW version 3.03
- Model 3140 ZWT
- Model 3141 USB Cable

All tests passed and confirmed intended use. Based upon the test results, it was concluded that the features of the NG System operated in accordance with the system requirements and conformed to user needs and its intended use.

The System Features Test Report ((b)(4) Trade Secret/CCI) is provided as Exhibit 5-9.

Reviewer Comment: The System Features Test Report was reviewed and found acceptable. The sponsor appears to have successfully completed the testing with the latest version of software/firmware.

Simulated Use Testing

The Simulated Use Testing provides an opportunity for users to accurately replicate the use of device/system to validate the behavior of the NG PG and ZOOM LATITUDE Programming System under simulated clinical use conditions. The primary focus of the testing is the interface between the system and user. This testing validated the PRM software release and the NG PG devices. The testing also included simulated implant and follow-up scenarios. The system under evaluation consisted of the PRM, the Model 2868 PRM software application (2868 PRM SW), the ZWT with Model 3141 USB cable, and an NG PG. The testing focused on the following:

- Installation of PRM application
- NG3 PG firmware
- Communication with implantable PG device using PRM application software
- Inductive communication using the wand
- RF communication using the ZWT and Model 3141 USB cable
- Simulated implant scenario
- Simulated follow-up scenario
- New PG Features

All tests passed and confirmed the intended use of the system under simulated clinical use conditions.

The Simulated Use Test Report (b)(4) Trade Secret/CCI is provided as Exhibit 5-10.

Reviewer Comment: The Simulated Use Test Report was reviewed and found acceptable. The sponsor appears to have successfully completed the testing with the latest version of software/firmware. There were no uncorrected failures.

Usability Engineering Study

The Usability Engineering Study was conducted to assess the usability of each of the NG/GALAXY system components' user interfaces and associated literature labeling. Testing demonstrated that no use errors that can lead to hazardous consequences are present. Any residual risk that remains would not be further reduced by any modifications to the design of the user interfaces and is outweighed by the benefits that may be derived from the use of the NG/GALAXY system.

The Usability Engineering Summary Report (b)(4) Trade Secret/CCI is provided as Exhibit 5-20.

Reviewer Comment: The Usability Engineering Summary Report was reviewed and found acceptable.

Model Number Validation

The Model Number Validation was conducted to verify the following:

- verify programmer software will successfully interrogate all PG models
- verify that the PRM and PG cans display the correct product name
- verify that the PG communicates with the programmer
- verify that the PRM SW application displays the correct features available for the given PG model
- verify that correct CID Nominal values and pseudo constants are loaded into the PG during manufacturing
- verify PG user programmable nominal parameters were set correctly during the manufacturing process

- verify the manufacturing process did not result in any leftover data in the PG which could cause confusion during implant or follow-up

There were no uncorrected test failures that occurred as a result of System Model Number Testing. Based on the results, the System Model Number Testing has passed.

The Model Number Validation Report (b)(4) Trade Secret/CCI is provided as Exhibit 5-21.

Reviewer Comment: The Model Number Validation Report was reviewed and found acceptable. This test report included testing for all NG3 models including the “mini” and “standard” models.

Design Verification Testing

Design verification testing (DVT) demonstrates that all system, device, capacitor and battery level requirements were met.

System DVT

System Design Verification Testing (Systems DVT) was performed to verify that systems consisting of two or more devices or elements meet design input requirements that define the interoperability and interaction of each device or element.

The system design verification testing used the following test articles:

- NG3 PG with Firmware Version E_v1.02
- Model 2868 Programmer Application SW version 3.03
- Model 3140 ZWT
- Model 3141 USB Cable

All system design verification tests passed per the methods and acceptance criteria established in the approved protocols.

The PG System DVT Report (b)(4) Trade Secret/CCI is provided as Exhibit 5-22.

Reviewer Comment: The System DVT Report was reviewed by the Mechanical/Manufacturing reviewer and found acceptable.

PG Mechanical DVT

Mechanical Design Verification Testing (MDVT) was performed to verify that the DYNAGEN, INOGEN and ORIGEN (NG2.5 and NG3) devices meet the mechanical design requirements as specified in the NG3 system requirement specification (SyRS) and hardware requirements specification (HWRS). Tests recommended in the Hardware REA (Exhibit 5-5) were included in this DVT.

There were no unexpected events or uncorrected failures during this MDVT. All mechanical design verification tests passed per the methods and acceptance criteria established in the approved protocols; therefore, the pulse generators meet the mechanical design hardware requirements.

The PG Mechanical DVT Report (b)(4) Trade Secret/CCI is provided as Exhibit 5-23.

Reviewer Comment: The PG Mechanical DVT Report was reviewed by the Mechanical/Manufacturing reviewer and found acceptable.

Corrosion DVT

Corrosion Design Verification Testing (Corrosion DVT) was performed to verify that the corrosion performance of (b)(4) Trade Secret/CCI when interfacing with (b)(4) Trade Secret/CCI on IS-1 leads meet the mechanical design corrosion requirements.

This testing was performed separate from the MDVT but was performed to verify that the component meets the mechanical design corrosion requirements. The (b)(4) Trade Secret/CCI are new for NG devices in comparison to predecessor products.

All tests passed per the method and acceptance criteria established in approved protocol. Based on the results of this testing, the design verification passed and therefore (b)(4) Trade Secret/CCI meets the input requirements specified in this document.

The Corrosion DVT Report (b)(4) Trade Secret/CCI is provided as Exhibit 5-24.

Reviewer Comment: The Corrosion DVT Report was reviewed by the Mechanical/Manufacturing reviewer and found acceptable.

PG Electrical DVT (includes EMI)

Electrical Design Verification Testing (EDVT) was performed to demonstrate that the DYNAGEN, INOGEN and ORIGEN devices meet the electrical design requirements as defined in the SyRS and HWRS.

Electrical design testing included telemetry communication, battery management, sensing, pacing, shocking, electro-magnetic interference (EMI), and other features.

There were no unexpected events or observed failures during this EDVT. All electrical design verification tests passed per the methods and acceptance criteria established in the approved protocols; therefore, the pulse generators meet the electrical design requirements.

The PG Electrical DVT Report (b)(4) Trade Secret/CCI is provided as Exhibit 5-25.

Reviewer Comment: In summary the sponsor has appeared to have successfully completed their electrical bench testing. There were no protocol deviations affecting the test methods or acceptance criteria. The sponsor includes Table 1 which describes the PG models covered under the scope of this document. As described by the sponsor, the hardware in the PG assembly for CRT-D models as listed in Table 1 contains a superset of the hybrid components and lead connections available in all of the PG models and may be used for all tests unless otherwise specified. Firmware system nominal settings may be used to configure CRT-D models to perform as DR models in applicable lead channels. Specific test protocols may call out a specific device type due to differences in system features, RF telemetry transceiver, header, or other component. In some cases, more than (b)(4) Trade Secret/CCI . If a component detail is not specified in the code, then it does not matter for that test which component is used. There are no further concerns. Note that the electrical EMI tests were reviewed as part of the EMC/Wireless consult.

Battery DVT

Boston Scientific conducted Battery Design Verification Testing (bDVT) to demonstrate that the (b)(4) Trade Secret battery used in NG2.5 meets the design requirements and specifications.

All tests passed per the method and acceptance criteria established in the approved protocol. Based on the results of this testing, the battery design verification passed. Therefore, the (b)(4) Trade Secret battery used in NG2.5 meets the requirements.

(b)(4) Trade Secret/CCI is provided as Exhibit 5-33.

Reviewer Comment: The Battery DVT Report was reviewed by the Mechanical/Manufacturing reviewer and found acceptable.

Capacitor DVT

Capacitor Design Verification Testing (Capacitor DVT) demonstrated that the capacitors used in the NG devices meets design requirements. Separate testing was conducted for capacitor used in NG3 devices and NG2.5 devices. Tests recommended in the Capacitor REA (Exhibit 5-6) were included in this DVT.

All capacitor design verification tests passed per the methods and acceptance criteria established in the approved protocols. Therefore, the capacitors meet the input requirements.

The NG3 Capacitor DVT Report (b)(4) Trade Secret/CCI is provided as Exhibit 5-34.
The NG2.5 Capacitor DVT Report (b)(4) Trade Secret/CCI is provided as Exhibit 5-35.

Reviewer Comment: The Capacitor DVT Reports were reviewed by the Mechanical/Manufacturing reviewer and found acceptable.

Parameter Interactions DVT

Parameter Interaction DVT was performed to verify the implementation of the parameter interaction system requirements and ensure that the Interactive Limits requirements were met. The testing included verification of evaluation conditions, applicability parameters, rule implementation, and violation feedback for individual parameter interaction system requirements. The intent of the tests is to show that the appropriate parameter interaction system requirements (device and programmer) have been correctly implemented. The testing verified the parameter interaction requirements which can produce warning and attention messages for the 2868 PRM application. In addition to the interaction rules, testing verified the messages displayed to the user and the parameters that can be programmed to resolve an interaction. The testing verified the expected parameter interactions and the expected violation feedback under a predefined set of parameter interaction test cases.

All parameter interaction design verification tests passed per the methods and acceptance criteria established in the approved protocols.

The Parameter Interactions DVT Report (b)(4) Trade Secret/CCI is provided as Exhibit 5-36.

Reviewer Comment: The Parameters Interactions DVT Report was reviewed and found acceptable.

PG Packaging DVT

Packaging Design Verification Testing (DVT) was performed to verify that the NG3 and NG2.5 packaging systems (sterile barrier packaging, secondary packaging, labels, and literature inside the box) meet all the design requirements after being exposed to challenge conditions as defined in the system requirements and the general specifications.

Testing verified through a series of integrity tests (Seal Strength, Dye Penetration, Visual Inspection, Particulate Content, Humidity, Marking Indelibility and Functional tests), that the packaging system is not adversely affected after exposure to sterilization cycles, climatic conditioning, distribution simulation, and after zero time, 2 years accelerated and 2 years real time shelf life time.

The verification of the packaging does not include device performance testing with the exception of the functional test. For the packaging performance and integrity tests, the evaluation is performed in three groups of devices to test at zero time, accelerated aging and real time aging. The sterile barrier integrity and seal strength tests performed at each of these times are limited to verify the integrity of the sterile barrier package and do not include any device test performance or functionality. Performance and functionality is covered by mechanical and electrical tests.

All packaging design verification tests passed per the methods and acceptance criteria established in the approved protocol. Two year accelerated aging test supports the 24 month shelf life of this product; the results of the Real Time aging will be ready (b)(4) Trade Secret/CCI

The PG Packaging Design Verification Test (b)(4) Trade Secret/CCI provided as Exhibit 5-37.

Reviewer Comment: The PG Packaging DVT Report was reviewed and found acceptable.

Component Qualifications

Component qualification is the testing performed to verify the capability of the supplier to provide components that conform to the Design Output Specification (DOS) defined by Boston Scientific.

Component qualifications were completed for all components that are new or modified for NG design and all components that have new suppliers. Table 5-4 denotes the major components that underwent qualification testing for the NG devices and the specific tests that the component was subjected. The table is followed by a brief description of what each test involves. These are general descriptions of tests performed on various components. The specific tests performed for each component is based on the specifications, use and the manufacturing process to which that part would be exposed.

Reviewer Comment: The Component Qualifications section was reviewed and found acceptable.

Design Analysis and Evaluation Testing

Design analysis testing and evaluation testing was performed to evaluate device robustness and correct implementation of the design intent. Design analysis testing and evaluation testing that were completed for this submission consisted of Capacitor Reform Evaluation Testing and Capacitor Vacuum Cycle Evaluation Testing.

Evaluation testing was conducted on the NG3 and NG2.5 capacitors to demonstrate capacitor performance after storage (b)(4) Trade Secret/CCI for different time intervals to evaluate the PG level reform schedule. This testing was done in support of the change to capacitor reform frequency. All results passed per the method and acceptance criteria established in the approved protocol. Based on the results of this test, the capacitors exhibited stable performance (b)(4) Trade Secret/CCI of the test interval.

NG3 Life Test (b)(4) Trade Secret/CCI Evaluation Report (b)(4) Trade Secret/CCI provided as Exhibit 5-49.

NG2.5 Life Test (b)(4) Trade Secret Evaluation Report (b)(4) Trade Secret/CCI is provided as Exhibit 5-50.

The intent of the vacuum process is to reduce the overall amount and variability of (b)(4) Trade Secret/CCI content inside the high voltage capacitor. Evaluation testing was conducted on the process to ensure it met intent.

Capacitor Vacuum Cycle Evaluation Report (b)(4) Trade Secret/CCI is provided as Exhibit 5-51.

Reviewer Comment: The Evaluation Reports were reviewed and found acceptable.

NON-CLINICAL LABORATORY STUDIES (AMENDMENT A001)

System Evaluation Plan/Report

Identical to original submission.

Ripple Effects Analysis and Test Roadmaps

Ripple effects analysis (REA) is the process for identifying which parts of the device/system are affected by the changes. When performing an REA, the impact of the change is analyzed to determine the effect on the system and the recommended testing to be performed to verify the change.

There were two (2) REAs created: one (1) Systems REA, and one (1) PRM REA. Changes were evaluated on a case by case basis to determine if additional testing was necessary to verify that the device continued to meet design requirements after the change. These REAs document the details of the changes (e.g. design specifications, materials, software changes, etc.) and analyze the changes for ripple into the rest of the design. Based on the analysis, the REA recommended additional testing to verify the impact of some of the changes. Test Roadmap was created for each REA to provide a “walk-through” of all testing required per the REA.

The REAs and test roadmaps are provided as follows:

- Exhibit 5-3: System REA (b)(4) Trade Secret/CCI This REA (b)(4) Trade Secret/CCI
- Exhibit 5-4: System REA Test Roadmap: (b)(4) Trade Secret/CCI
- Exhibit 5-5: PRM REA (b)(4) Trade Secret/CCI): This REA (b)(4) Trade Secret/CCI
- Exhibit 5-6: PRM REA Test Roadmap: (b)(4) Trade Secret/CCI

Reviewer Comment: The REA and Test Roadmap documents were reviewed and found acceptable. The sponsor appears to have done the appropriate analysis to determine which testing is required for the changes.

Design Validation Testing

System Features Testing

Identical to original submission.

Simulated Use Testing

Identical to original submission.

Usability Engineering Study

Identical to original submission.

Design Verification Testing

Design verification testing (DVT) demonstrates that all system, device, capacitor and battery level requirements were met.

Model 2909 MAU Software Design Verification Test

A full SW DVT was conducted to verify that the model 2909 MAU Software v9.02 met all applicable software requirements.

All MAU SW DVT test cases passed with one uncorrected failure. The MAU 2909 PRM SW DVT Report (b)(4) Trade Secret/CCI provided as Exhibit 5-10.

A failure was observed with an external printer connected to the PRM via a parallel cable and multiple reports selected to be printed. Although all reports print successfully, an external printer error dialog is shown incorrectly after printing is complete. Tests were rerun with a USB cable connecting the external printer and the PRM. The rerun successfully verified MAU SW capability to print reports appropriately to an external printer. Safety analysis was performed and indicated no increased risk, as the failure is not safety related and does not affect the ability of the system to provide life-saving therapy and diagnostic functions.

Reviewer Comment: The MAU SW DVT documents were reviewed and found acceptable. The one uncorrected failure does not appear to be a safety concern and is therefore acceptable.

PRM Platform Design Verification Test

The PRM Platform Design Verification test was performed to ensure that systems consisting of two or more devices or elements meet design input requirements that define the interoperability and interaction of each device or element.

The PRM Platform design verification testing used the following test articles:

The device(s) under test for the ZOOM LATITUDE Programming System are:

- Model 3140 ZWT
- Model 3120 PRM
- Model 2909 MAU System Software version 9.02
- Model 3141 USB Cable

All design verification tests passed per the methods and acceptance criteria established in the approved protocols.

The PRM Platform System DVT (b)(4) Trade Secret/CCI is provided as Exhibit 5-11.

Reviewer Comment: The PRM Platform System DVT documents were reviewed and found acceptable.

PG/PRM System DVT

Identical to original submission.

ZWT Electrical Design Verification Test (includes EMI)

Electrical Design Verification Testing (EDVT) was performed to ensure that the ZWT met electrical requirements, as defined in system requirements specification 590630-008. Areas tested included electromagnetic immunity and compatibility (EMI/EMC) testing, electrical safety testing and general functional testing.

The ZWT Electrical DVT Report 1108104 (Exhibit 5-13) is the overarching BSC report that covers all EDVT testing. This includes general functional testing that is completed at BSC, as well as standards based testing which is completed by certified test labs.

The ZWT Electrical Safety Test Report; Medical Electrical Equipment Basic Safety and Essential Performance EN 60601-1 1114622 (Exhibit 5-14) covers all EN 60601-1 electrical and mechanical safety testing performed by certified test lab (b)(4) Trade Secret/CCI

The ZWT Immunity and Emissions Test Report 60601-1-2 1114612 (Exhibit 5-15) covers all IEC 60601-1-2 and EN 301 489-27 EMI/EMC testing performed by certified test lab (b)(4) Trade Secret/CCI

The PRM & ZWT (b)(4) Trade Secret/CCI Report, Assessment, and Certificate (b)(4) Trade Secret/CCI (Exhibit 5-16) contains a clause by clause conformity assessment to EN 60601-1, performed by certified test lab (b)(4) Trade Secret/CCI. All applicable assessments passed.

All design verification tests passed per the methods and acceptance criteria established in the approved protocol.

Reviewer Comment: In summary the sponsor has appeared to have successfully completed their electrical bench testing. There were no protocol deviations affecting the test methods or acceptance criteria. There are no further concerns. Note that the electrical EMI tests were reviewed as part of the EMC/Wireless consult.

ZWT Mechanical Design Verification Test

Mechanical Design Verification Testing (MDVT) was conducted to ensure that the ZWT met mechanical requirements, as defined in system requirements (b)(4) Trade Secret/CCI. The mechanical DVT was performed to ensure that the mechanical requirements of the ZWT were met, including, but not limited to, operational environment, vibration, mechanical shock, and thermal shock.

All mechanical design verification tests passed per the methods and acceptance criteria established in the approved protocol.

The ZWT Mechanical DVT (b)(4) Trade Secret/CCI is provided as Exhibit 5-17.

Reviewer Comment: The ZWT Mechanical DVT Report was reviewed by the Mechanical/Manufacturing reviewer and found acceptable.

ZWT Packaging Design Verification Test

Packaging Design Verification Testing (DVT) was performed to verify that the ZWT packaging system meets all the design requirements after being exposed to challenge conditions as defined in the system requirements and requirements related to Packaging and Labeling required by (b)(4) Trade Secret/CCI. Device package performance was verified and confirmed that protection of device electrical, mechanical, and safety performance was achieved. Labeling performance was verified and confirmed that label adhesion and legibility requirements were met.

All packaging design verification tests passed per the methods and acceptance criteria established in the approved protocol.

The ZWT Packaging and Labeling DVT Report (b)(4) Trade Secret/CCI provided as Exhibit 5-18.

Reviewer Comment: The ZWT Packaging and Labeling DVT Report was reviewed by the Mechanical/Manufacturing reviewer and found acceptable.

Component Qualifications

Component Qualifications that were completed for the ZWT are summarized in Table 2-4. All component qualifications passed and confirmed the main control PCB and antenna PCB for the ZWT met Boston Scientific specifications.

Reviewer Comment: The Component Qualifications was reviewed by the Mechanical/Manufacturing reviewer and found acceptable.

ZWT DESIGN ANALYSIS TESTING

Design analysis testing and evaluation testing was performed to evaluate device robustness and correct implementation of the design intent. The design analysis testing conducted on the ZWT and PRM demonstrated ZWT compliance to design intent for the processing of fault scenarios. Tests included evaluating the behavior of ZWT for antenna failure, invalid operational software, hardware faults, invalid bootloader software, and USB cable connection.

The ZWT System Design Analysis Test Report (b)(4) Trade Secret/CCI provided as Exhibit 5-21.

Reviewer Comment: In summary the sponsor has appeared to have successfully completed their ZWT Design Analysis Testing. There are no further concerns.

EMC/EMI AND WIRELESS

The EMC/Wireless reviewer reviewed the EMC and Wireless information for the original submission and for **Amendment A001**. He identified four deficiencies which need addressing, three for EMC and one for wireless.

In **Amendment A002**, the sponsor provided a response to the four deficiencies. He reviewed the response and found that the sponsor did not fully address deficiency #3. The remaining deficiencies were adequately addressed. An additional question was asked interactively to the sponsor for deficiency #3. The sponsor response was reviewed and found acceptable.

SOFTWARE (ORIGINAL SUBMISSION)

The sponsor provided an overview of Boston Scientific medical device software development and documentation process. They provided the informational elements outlined in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Section 3 (FDA, CDRH, issued May 29, 1998). Additional information elements mentioned in the guidance are provided in Exhibit 2-3: Software Development Overview, per FDA Guidance for NG device FW and PRM 2868 application software.

The documentation provided by the sponsor was reviewed in accordance to the guidance document, Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005. The following areas were reviewed:

- Level of Concern – PG FW and PRM SW
- Software Description – PG FW and PRM SW
- Device Hazard Analysis – PG FW and PRM SW
- Software Requirements Specification (SRS) – PG FW and PRM SW
- Architecture Design Chart – PG FW and PRM SW
- Software Design Specification (SDS) – PG FW and PRM SW
- Traceability Analysis – PG FW and PRM SW
- Software Development Environment Description – PG FW and PRM SW
- Verification and Validation Documentation – PG FW and PRM SW
- Revision Level History – PG FW and PRM SW
- Unresolved Anomalies – PG FW and PRM SW

Review Comment: No deficiencies were identified during the initial review of this documentation. The sponsor provided documentation was found acceptable and there were no further concerns.

SOFTWARE (AMENDMENT A001)

The ZOOM LATITUDE Programming System includes software programs that execute on the PRM and the ZWT. The PRM software application used to interrogate and program NG PGs is the Model 2868 Programmer Application Software. This software application is started by the Multiple Application Utility (MAU) software application via user menu selection or a PG auto-identification feature called (b)(4) Trade Secret/CCI. The 2868 Programmer Application Software exchanges data with the PG using PRM operating system software (software radio/MICS device driver/common protocols) and the ZWT external antenna accessory for MICS RF telemetry. Telemetry continues to be supported for BSC's ISM/SRD band PGs and there are no changes to this functionality. Inductive telemetry (wanded, non-RF) continues to be supported for all BSC PGs and there are no changes to this functionality.

The documentation provided by the sponsor was reviewed in accordance to the guidance document, Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005. The following areas were reviewed:

- Level of Concern – PRM and ZWT SW/FW
- Software Description – PRM and ZWT SW/FW
- Device Hazard Analysis – PRM and ZWT SW/FW
- Software Requirements Specification (SRS) – PRM and ZWT SW/FW
- Architecture Design Chart – PRM and ZWT SW/FW
- Software Design Specification (SDS) – PRM and ZWT SW/FW
- Traceability Analysis – PRM and ZWT SW/FW
- Software Development Environment Description – PRM and ZWT SW/FW

- Verification and Validation Documentation – PRM and ZWT SW/FW
- Revision Level History – PRM and ZWT SW/FW
- Unresolved Anomalies – PRM and ZWT SW/FW

Review Comment: No deficiencies were identified during the initial review of this documentation. The sponsor provided documentation was found acceptable and there were no further concerns.

MANUFACTURING AND QUALITY SYSTEM

The manufacturing and quality system in section 3 of the original submission and in section 3 of **Amendment A001** was reviewed by the Mechanical/Manufacturing reviewer. Overall his Mechanical Engineering and Manufacturing Review did not identify any major deficiencies. The firm has provided adequate component level DVT as well as system level DVT to support the safety and effectiveness of the proposed devices (PGs and ZWT). Additionally, the manufacturing sections of this review were complete and adequate. The firm provided appropriate documentation to support the verification and validation of new processes for the PGs as well as appropriate information about the contract manufacturer for the ZWT. There were no outstanding concerns related to his review.

ANIMAL TESTING

The Animal Study reviewer reviewed the Animal Testing information included in the original submission. There was no animal testing included in **Amendment A001**. She identified three deficiencies which need addressing.

In **Amendment A001**, the sponsor provided a response to the three deficiencies. She reviewed the response and found that the sponsor fully addressed all the deficiencies. There are no further concerns.

LABELING

The DYNAGEN, INOGEN, AND ORIGEN literature and labeling are based on the INCEPTA, ENERGEN, and PUNCTUA predecessors. Changes to the literature includes changes due to new device functionality, the new PRM accessory, and clarification for existing features and projected device longevity. Several minor changes have been included for completeness regarding supplemental forms, the patient ID card, and the errata sheet.

The currently approved Patient Handbooks used with predecessor devices will be used with NG devices. No changes are proposed to the Patient Handbooks.

PRM (Amendment A001)

The operator's manual for the PRM describes the operation of the model 3120 ZOOM Latitude Programming System and its accessories. It is provided as Exhibit 9-1: PRM Operator's Manual 1114214 (357434-007).

Changes to the operator's manual include updates for clarity, ease of use, and adding use of the ZWT. See Section 9.1.6 for a description of changes.

The manual is provided to customers as a printed hard copy and is also available on the BSC website. Note that online labeling is provided as a convenience to customers.

Intended use, contraindications, potential adverse effects, warnings and precautions, and operator's manual changes for the PRM are provided in the sub-sections below.

ZWT (Amendment A001)

The reference manual for the ZWT describes the operation of the device. It contains general usage information, safety notes, and a complete explanation of how to use the device. The reference manual is provided as Exhibit 9-3: ZWT Reference Manual (1111853).

The quick start guide for the ZWT describes how to set up the device prior to use. The quick start guide is provided as Exhibit 9-4: ZWT Quick Start Guide (1110449).

The reference manual and quick start guide are provided to customers as a printed hard copy and are also available as a convenience to customers on the BSC website.

Intended use, contraindications, potential adverse effects, and warnings and precautions created for the ZWT are provided in the sub-sections below. Since the ZWT is a new device change tables are not provided.

Reviewer Comment: The labeling changes were reviewed and found acceptable. The Clinical reviewer reviewed the labeling as part of his clinical review and found it acceptable. There are no further concerns. Also regarding the NG quadripolar CRT-D device, BSC updated their labeling to include compatibility specifically with the St. Jude lead. The labeling regarding the compatibility with St. Jude lead is in Exhibit 9-2: Physician Technical Manual CRT-D of the submission. The labeling is identical to the draft labeling which was provided in pre-submission Q120409. This draft labeling was reviewed by FDA at that time. However after further discussion and a request by FDA, the labeling was modified to state that compatibility with the St. Jude Quartet IS4 lead has been demonstrated through chronic in-vivo animal GLP testing.

OTHER REVIEW ELEMENTS

The following areas are not relevant for the subject review:

- Biocompatibility
- Sterilization, shelf-life
- Marketing
- Post Market

CONCLUSION/RECOMMENDATION

The sponsor responses to the deficiencies have been found to be acceptable. The sponsor has shown the devices included in this submission to be safe and effective at this time. I recommend that the sponsor receive an **APPROVAL** letter.