

SUMMARY OF: P910077/S140

BOSTON SCIENTIFIC LATITUDE COMMUNICATOR MODELS 6460, 6280, 6290, 6250, 6498, AND 6476

Executive Summary

Boston Scientific is requesting approval for modifications to the LATITUDE NXT Patient Management System. The changes proposed are briefly described below:

- LATITUDE NXT 2.0 System Server Software (Model 6460) – primary changes include support for NG3 family of PGs using MICS RF band (402-405MHz)
- LATITUDE Wave Communicators, Models 6280 (mechanically equivalent to currently approved Model 6498 except the internal 2G cellular connectivity has been removed, added support for Cognis/Teligen/Progeny) and 6290 (new)
- Updates to communicator software of currently marketed 6498
- Server software support for the LATITUDE G2 Communicator Model 6476 – migration to NXT 2.0 system, only a change in which server is used to support device communications
- Optional 3G cellular connectivity is provided to Models 6280, 6290, and 6498 via an external non-medical device adapter (Model 6295) connected via USB plug.

Overall, the changes did not introduce novel functions into the system. The communicators are not life-supporting and do not provide continuous, real-time data for physicians. In the original submission (P910077/S140), the sponsor adequately addressed electrical and mechanical design verification, RF Telemetry information, biocompatibility, clinical/post-market surveillance, and software verification. The main concerns found during the first round of review included issues with the usability testing, EMC/EMI and a minor labeling issue. The sponsor was sent a Major Deficiency Letter on 18 February 2014 and addressed these issues in Amendment 1.

System Description

LATITUDE Systems Software (Server)

The LATITUDE NXT Patient Management System Application Server (also referred to as the server software) supports the various features needed to offer a viable remote monitoring service to physicians. This Server is responsible for receiving, storing, and managing clinical device data gathered from compatible implanted PGs, Communicators, and optional external health sensors (blood pressure monitor and weight scale). The Server presents the stored data on the LATITUDE website to authorized users.

Communicators Supported by the LATITUDE NXT System

Wave Communicator Model 6280

The Model 6280 Wave Communicator is a second generation release of the Wave Communicator and introduces 3G cellular network connectivity as an optional accessory. The

Model 6280 Communicator is mechanically equivalent to the production released Model 6498, except that the internal 2G integrated cellular connectivity component has been removed from the printed circuit assembly in favor of an optional external 3G adapter. The Model 6280 Communicator uses standard analog telephone connectivity with the optional 3G cellular capability provided by Model 6295 USB Cellular Adapter. The Communicator will be provided with an AC power supply, standard telephone cord, patient user manual, and quick setup guide. The model 6280 Communicator supports the COGNIS, TELIGEN, PUNCTUA, ENERGEN, INCEPTA and INGENIO families of PG devices using ISM band telemetry.

Wave Communicator Model 6290

The Model 6290 Wave Communicator is a second generation release of the Wave Communicator that utilizes the 402 – 405 MHz Medical Implant Communication Systems (MICS) RF band for wireless communication with the next generation NG3 BSC implantable PGs. The Model 6290 is also mechanically equivalent in size and shape to the previous Model 6498; however, Model 6290 uses a new printed circuit board and circuit assembly to incorporate design changes. The Model 6290 Communicator will have both analog telephone and cellular capabilities. The optional cellular capability is provided by Model 6295 USB Cellular Adapter. The Communicator will be provided with an AC power supply, standard telephone cord, patient user manual, and quick setup guide. The Model 6290 Wave Communicator supports interrogation of the AUTOGEN, ORIGEN, DYNAGEN, and INOGEN family of PG devices using MICS band telemetry.

Wave Communicator Model 6498

The Model 6498 Communicator is the first generation Wave Communicator used to connect INGENIO brady PG devices to the LATITUDE Patient Management System. This approved and production-released Wave Communicator model will be updated with the same software (v1.51.00) as the new Model 6280 Wave Communicator. Model 6498 will continue to use internal 2G capability, but will also be compatible with the optional external Model 6295 USB Cellular Adapter for 3G connectivity. There are no other changes to the existing Model 6498 Communicator. The Model 6498 Communicator will now support the COGNIS, TELIGEN, PUNCTUA, ENERGEN, INCEPTA families of PG devices, in addition to INGENIO, using ISM band telemetry.

Latitude Communicator Model 6476

The Model 6476 LATITUDE Communicator is the currently approved G2 RF Communicator in use on the existing LATITUDE System. Data from Model 6476 Communicators will be migrated from the existing LATITUDE System server to the LATITUDE NXT System server. There are no changes to the Model 6476 Communicator hardware or software; however, due to server software changes on the NXT 2.0 System, the current patient health questions available on the Model 6476 will be deactivated.

Pulse Generators Supported by the LATITUDE System

For reference, below is a list of pulse generators supported by the LATITUDE system:

ADVANTIO, INGENIO, VITALIO, FORMIO Pacemaker Devices

- Models: K062, K063, K064, K065, K066, K067, K172, K173, K174, K175, K176, K177, K272, K273, K274, K275, K276, K277, K278, K279

INVIVE, INTUA, INLIVEN CRT-P Resynchronization Devices

- Models: V172, V173, V272, V273, V274, V275

COGNIS 100 CRT-D Resynchronization Devices

- Models: N118, N119, SRD-1 conversion R1N119

TELIGEN 100 ICD Devices

- Models: E102, E110

PUNCTUA, ENERGEN, INCEPTA ICD Devices

- Models: E050, E051, E052, E053, E140, E141, E142, E143, E160, E161, E162, E163

PUNCTUA, ENERGEN, INCEPTA CRT-D Resynchronization Devices

- Models: N050, N051, N140, N141, N160, N161, N164

ORIGEN, INOGEN, DYNAGEN AUTOGEN, ICD Devices

- Models: D000-000, D001-000, D002-000, D003-000, D010-000, D011-000, D012-000, D013-000, D020-100, D021-100, D022-100, D023-100, D030-100, D031-100, D032-100, D033-100, D050-000, D051-000, D052-000, D053-000, D140-000, D141-000, D142-000, D143-000, D150-100, D151-100, D152-100, D153-100, D160-100, D161-100, D162-100, D163-100

ORIGEN, INOGEN, DYNAGEN, AUTOGEN CRT-D Resynchronization Devices

- Models: G050-100, G051-100, G056-100, G058-100, G140-100, G141-100, G146-100, G148-100, G150-100, G151-100, G154-100, G156-100, G158-100, G160-100, G161-100, G164-100, G166-100, G168-100

External Health Sensors For Home Health Monitoring

The weight scale (BSC Model 6487) and blood pressure monitors (BSC Models 6452 and 6483) are optional components of the LATITUDE NXT system. Each of these components, when used by the patient, automatically transmits measurements over a Bluetooth wireless communication connection to the patient's Communicator. The Bluetooth communication accessory (used with Wave Communicators) plugs into the back of the communicator and is manufactured by Delta Mobile (distributed as BSC Model 6454). The Communicator automatically sends these measurements to the LATITUDE NXT Server where they are made available for the clinician's review. Although the patient may use the blood pressure monitor and weight scale at any time during the day, only one daily reading is reported on the LATITUDE NXT website.

External USB 3G Cellular Adapter

The Model 6295 Cellular Adapter is an optional non-medical device accessory that can be connected to the USB ports of Communicator Models 6280, 6290, and 6498 to provide 3G cellular connectivity. The Cellular Adapter contains a Cinterion PHS8-P cellular module, certified by Cinterion to meet cellular standards, that is responsible for data transfer to and from the LATITUDE NXT Server; it is the cellular equivalent of a landline modem. A SIM card issued by the cellular service carrier that resides within the adapter is accessed by the Cinterion module and is used to provide secure communications, authentication, and identity of the

Communicator on the cellular network. In North America, the SIM card will be issued by AT&T and activated for use on AT&T and their partner networks.

Indications for Use

The LATITUDE NXT Patient Management system is intended to remotely communicate with a compatible Boston Scientific implanted device and transfer data to a central database. The LATITUDE NXT system provides patient data that can be used as part of the clinical evaluation of the patient.

Alerts

The LATITUDE NXT system generates alert notifications for a number of conditions which vary depending on the implanted device model. There are two levels of alert conditions: red alerts and yellow alerts. The alerts are designed to notify clinic users of potential health conditions or device clinical events. Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care. Alerts can be verified by viewing information on the LATITUDE NXT website and by using a Programmer to review additional supporting diagnostic information stored in the implanted device.

Labeling

The patient manual for Models 6280 and 6290 LATITUDE Wave Communicators describes the operation of the Communicator and accessories. The patient manual contains general use information, important safety notes, and a complete explanation of how to use the system.

The LATITUDE Communicator Installation and Quick Reference Guide is provided along with the Patient Manual. The existing approved Patient Manual for Communicator Model 6498 is unaffected by the implementation of LATITUDE NXT 2.0.

A clinician manual provides information on LATITUDE Communicators and their intended use to remotely communicate with an identified implanted device, via RF technology, within the patient's home. The manual is provided to Clinicians as a printed hard copy and is also available on the LATITUDE NXT website.

REVIEWER COMMENTS: The sponsor was asked the following deficiency in the 18 February 2014 Major Deficiency Letter:

You have provided the LATITUDE Communicator Patient Manual and the LATITUDE NXT Clinician Manual in Exhibits 5-01 and 5-04, respectively, of your submission. However, it is unclear what has changed from previous versions of these manuals. Please provide a side-by-side comparison of the changes made to these manuals from previous versions. Alternatively, please provide a redlined version of each of the manuals listed above.

The sponsor provided redlined versions of the Patient Manual and Clinician Manual in Amendment 1. A change table was also included. Updates to the labeling were made for clarification purposes and to include the new Communicator version, among other minor changes. I have no concerns with these changes and find the labeling to be acceptable.

Software

LATITUDE NXT System Release 2.0 includes the Wave Communicator Software, Server Software, EMR export application and collectively refers to the following four software versions being released:

- LATITUDE NXT Server software version 2.00.01
- LATITUDE Wave Communicator Model 6290 software version 2.01.00
- LATITUDE Wave Communicator Model 6498/6280 software version 1.51.00
- LATITUDE NXT EMR export application software version 2.00.00

The Formal Design Verification testing started with a full set of tests being executed for Communicator software 2.00.00 (Model 6290) and 1.50.00 (Model 6498/6280). LATITUDE NXT Communicator software versions 2.00.00 (Model 6290) and 1.50.00 (Model 6498/6280) were updated to correct an observation, creating Communicator software versions 2.01.00 (Model 6290) and 1.51.00 (Model 6498/6280). A Ripple Effect Analysis was performed to determine the amount of additional testing required due to the software changes introduced.

The System, Communicator and regulated server software design verification test results are applicable to this submission. The additional software testing that covers the nonregulated software included in this submission (portions of the System Server Software, EMR Export Application, OTS Software, and Subsystem Technical Architecture) is included for completeness only.

Wave Communicator (Models 6498, 6290, and 6280) Software – Version 2.01.00 and 1.51.00

Level of Concern: Major

Software Description

The primary functions of the updated Wave Communicator (2.0) are unchanged from the existing Wave Communicator (1.0). They are:

- To interrogate a patient's PG per a pre-defined schedule.
- To identify alert conditions present in the patient's PG.
- To receive measurements from assigned external sensors.
- To communicate PG data and alert conditions to the LATITUDE NXT Server.
- To communicate sensor data and alert conditions to the LATITUDE NXT Server.
- To receive and apply configuration updates from the LATITUDE NXT Server.

The Communicator initiates an interrogation of the patient's PG (using RF technology) at times specified by the patient's physician. Alternately, an interrogation can be initiated by the patient. The Communicator also initiates an interrogation daily to check for alerts, regardless of what follow-up schedule the physician has chosen.

After the PG interrogation completes, the PG data and any data received from the optional external sensors are securely uploaded by the Communicator to the Device Services portion of the LATITUDE NXT Server through a telephone landline or cellular network. The proposed new system adds 3G cellular capability but still supports the current market-approved dial-up telephone connection and 2G cellular connection.

Software Comparison between LATITUDE Wave Communicator 1.0 (predecessor) and LATITUDE Wave Communicator 2.0 (subject of this submission)

SW Features	Wave™ Communicator 1.0	Wave™ Communicator 2.0
Alert detection and processing	Fixed weight gain and fixed loss weight alerts.	A configurable weight gain alert. No weight loss alert.
PG Telemetry	Uses wireless RF telemetry (ISM and SRD bands) to communicate with the PG.	Uses wireless RF telemetry (MICS, ISM, and SRD bands) to communicate with the PG.
Server Connectivity	Landline and 2G cellular connectivity from Communicator to the Server.	Landline 2G cellular, and 3G cellular connectivity from Communicator to the Server.
Device Support	Ingenio PG device family supported.	Supports the NG3, Ingenio, Cognis/Teligen, and Progeny PG device families.

Software Verification

LATITUDE NXT 2.0 Communicator Design Verification Testing was performed to verify compliance of the Jaguar Communicator 2.0 version 2.01.00 (Model 6290) Application software as well as version 1.51.00 Application Software running on Communicator models 6498, 6288, and 6280. The cellular adapters (models 6295 and 6296) were also tested in conjunction with these communicators. All testing was completed with zero uncorrected failures.

REVIEWER COMMENTS: The sponsor has provided descriptions of the Software Requirements Specification (SRS), Software Design Specification (SDS), Traceability Analysis, Architecture Design Chart, and Software Development Process in Exhibit 2-03 of the submission. Full traceability and verification/validation documentation are also provided. Based on the information provided, I feel that this new version of software is adequate and does not present risks to the patient or physician. The changes from previous versions are very minor and do not introduce major changes to the software. The communicators function similarly to previous versions. The sponsor has verified that the software meets all specified requirements with zero test failures. I do not have any further concerns and find this information acceptable.

RF Telemetry/ Wireless Coexistence

The Wave Communicator includes a PG RF Telemetry subsection that supports world-wide use of the Medical Implant Communication System (MICS) with one design. The PG RF telemetry subsystem implements a frequency hopping scheme using 10 equally spaced 300 kHz channels between 402 – 405 MHz. The Wave Communicator has an embedded antenna that is integrated into the PCB design. Additional board level shielding included reducing noise in the MICS band.

The Wave Communicator supports the use of the optional external LATITUDE NXT USB Cellular Adapter which provides a cellular interface to send data to the LATITUDE NXT Server. The Cinterion PHS8-P cellular module supports five-band UMTS 3G (800/850/900/1900/2100 MHz)/quad-band 2G operation (850/900/1800/1900 MHz) to provide support in North America, Europe, and Australia/New Zealand, Brazil, Israel, and Japan. The LATITUDE NXT USB Cellular Adapter SIM card holder will be populated with an AT&T cellular SIM card.

REVIEWER COMMENTS: The sponsor has addressed all aspects of the RF/Wireless FDA Guidance. I have reviewed this information and find it acceptable. The one concern I had was that the sponsor conducted “informal testing” for wireless coexistence. The results of this testing seem to be favorable, however the sponsor did not provide any test plans or reports. I consulted an RF expert on this issue, and he believes that because the device only transmits data every 14 days and is not a life-sustaining device, then he would accept the informal testing as sufficient. I agree with his assessment. I believe this device has the ability to adequately transmit data to meet the system requirements. This information is acceptable.

Manufacturing

The LATITUDE Wave Communicators, Models 6280, 6290, and 6498 are manufactured (includes packaging and labeling) by (b)(4) TS/CCI (b)(4) TS/CCI manufactures the (b)(4) TS/CCI . The sponsor has provided the quality system information for the (b)(4) TS/CCI and the specific manufacturing process and controls applicable to LATITUDE Wave Communicators.

*REVIEWER COMMENTS: A manufacturing consultant provided a consult during the first round of review to review the manufacturing information described above, including all exhibits listed. Overall, he did not have any concerns regarding the manufacturing information provided and I agree with his assessment. **This information is acceptable.***

System Evaluation/Non-clinical Testing

The system design verification testing was performed in order to ensure that the system requirements were met. All testing was completed with zero uncorrected failures. The testing activities are described in the sections below.

Electrical Design Verification Testing

The Electrical Design Verification Testing (EDVT) was performed to ensure that the electrical requirements of the Wave Communicator Models are met as defined in the System Requirements Specification. EDVT is part of a total system test plan that includes electromagnetic compatibility, modem, radio compliance, electrical safety and various functional tests. The sponsor states that all testing was completed with zero uncorrected failures.

Electrical Safety (Electrical Engineer’s Comments): In summary the sponsor has appeared to have successfully completed their electrical bench testing. For the Model 6290 and 6280 EDVTs, there were no protocol deviations affecting the test methods or acceptance criteria. There are no further concerns.

The sponsor has successfully demonstrated compliance to IEC 60601-1:2005 for Model 6290/6280 and Model 6498. There are no further concerns.

For the Modem Compliance Report, Model 6280 was not tested. It was deemed that Model 6290 was the worst case model and the test results would represent both models. This appears to be acceptable since the modem is the same.

The sponsor has also demonstrated compliance to IEC60601-1 for the electrical safety for clauses: 5.7 (Humidity Pre-Conditioning), 8.4.3 (Residual Voltage), 8.7 (Leakage Currents), 8.8.3 (Dielectric Strength), and 11.1.1 (Part Temperature Limits). There are no further concerns.

EMC/EMI (Electrical Engineer's Comments): The following deficiency was sent to the sponsor in the 18 February Major Deficiency Letter:

Your EMC test results indicate passing individual tests according to your defined Performance Criteria A – D. (b)(4) TS/CCI

Please provide a test matrix explaining the individual results for each device (model 6280 and 6290) and operating mode with respect to your defined Performance Criteria. Additionally please justify how the results of Performance Criteria B, C, and D in this matrix are considered a pass according to the compliance criteria defined in Section 6.2.1.10 of IEC 60601-1-2:2007.

The electrical engineer reviewed the sponsor's response to this deficiency in Amendment 1. He found remaining concerns with this response and requested a follow-up deficiency be sent via e-mail. The sponsor responded to this deficiency via e-mail and provided a response that was found adequate by the electrical engineer. There were no remaining concerns.

The electrical engineer also identified the following deficiency in the sponsor's labeling, which was sent to the sponsor in the 18 February Major Deficiency Letter:

You provided EMC labeling information beginning on page 65 of your Patient Manual and page 155 of your Clinician Manual. However we could not find your essential performance in either manual. IEC 60601-1-2:2007 requires that the essential performance is included in the technical description (requirement 5.2.2.1 g). Please update your labeling to meet this requirement of IEC 60601-1-2:2007.

The electrical engineer reviewed the sponsor's response in Amendment 1 and found that The sponsor has provided their essential performance on page 63 of the Patient Manual and on Page 151 of the Clinician Manual. The sponsor has adequately addressed this concern.

Mechanical Design Verification Testing

The Mechanical Design Verification Testing (MDVT) was performed to ensure that the mechanical requirements of the Wave Communicator Model 6290 and 3G cellular adapter model 6295 were met as defined in the System Requirements Specification. All testing was completed with no uncorrected failures.

The existing model 6498 Communicator hardware was unchanged with this release and all previously completed mechanical testing remains applicable.

The new Model 6280 Communicator is a modified Model 6498 Communicator with the integrated cellular component removed. The removal of the internal cellular component did not impact mechanical DVTs and all previously completed mechanical testing remains applicable.

*REVIEWER COMMENTS: A mechanical engineer provided a consult for this section of the submission in the first round of review. He did not have any concerns regarding this testing, and I agree with his assessment. **This information is acceptable.***

Component Qualification Tests

The purpose of component qualification is to verify a manufacturer's ability to provide software and/or hardware that meet BSC CRM specification requirements. Components are assessed through the following:

- Visual Inspection - Sample components are subjected to external or internal visual inspection for defects or damage per appropriate standards, and to verify that the materials, construction, and workmanship are in accordance with defined specifications.
- Physical Dimensions - to verify that components met the physical dimension specifications as derived from the design requirements.
- Electrical Test - Components were measured for appropriate electrical properties such as voltage, insulation resistance, dissipative factor, and/or dielectric strength.

*REVIEWER COMMENTS: A mechanical engineer provided a consult to review the Component Qualification Tests in this submission during the first round of review. All qualification activities are described in the quality plan and are controlled by the quality system. There were no concerns with this section of the review. I agree with his assessment and have no further concerns. **This information is acceptable.***

Animal Studies

Animal studies were not performed for the LATITUDE NXT System.

Biocompatibility Studies

The LATITUDE Wave Communicator is not categorized as a surface (skin) contacting device, nor does it fall within the category of limited exposure. The examples and boundaries contained in EN ISO 10993 for limited exposure devices are in semipermanent applications w/ skin contact of up to 24 hours. The duration of skin contact is estimated to be less than 5 seconds per touch for the Communicator. However, to eliminate any questions regarding biocompatibility the material and colorant composition were evaluated during the original LATITUDE NXT project to see if they had any potential biocompatibility issues. Note that this biocompatibility analysis was performed on the 1.0 Communicators (the previous versions of the subject devices). There were no skin irritations/biocompatibility issues observed during this analysis.

The sponsor states that there were no material changes made that would affect the previous biocompatibility analysis performed in reference to the 2.0 Communicators.

REVIEWER COMMENTS: the biocompatibility analysis provided is adequate. This device is not a surface (skin) contacting device or a limited exposure device and this analysis was performed to eliminate any potential questions regarding the materials used. I have no concerns with these materials and believe this information is adequate.

Safety Risk Management Activities

The sponsor performed a hazard analysis, reliability predication, security risk assessment, and failure modes effects analysis (FMEA) for the devices and software included in this submission. These analyses are reviewed below.

Hazard Analysis

A hazard analysis was performed for the LATITUDE NXT 2.0 system. Potential hazards associated with the intended use and functionality of the LATITUDE NXT 2.0 system were evaluated. The analysis identified and documented potential hazards that could result from using the system. Mitigations have been implemented to ensure identified hazards introduced by the LATITUDE NXT 2.0 system have been adequately addressed.

The Hazard Analysis includes all components of the LATITUDE NXT 2.0 system (Communicator, external sensors, and System Server Software), in addition to the interactions of the system with the families of implanted devices that are referenced in this submission.

The scope of this analysis specifically excludes those hazards that are mitigated within an RF enabled pulse generator. Hazards identified in this analysis that are mitigated within those devices are traced to the hazard analysis for those devices. The adequacy of controls and mitigations has been peer reviewed and the LATITUDE communicators and associated components have been deemed acceptable for human use.

REVIEWER COMMENTS: A wide variety of hazards were assessed, ranging from hazards that could lead to early battery depletion to security hazards present by having an Internet-based system. Hazards associated with human factors were also assessed. Mitigations were identified and incorporated into various components of the system, including the server (authentication mechanisms, integrity mechanisms), the Communicator (interrogation frequency limits, authentication and integrity mechanisms, interfaces for the patient to see alerts, tamper resistance), and the PG (limits on command accepted via the Communicator, integrity and authentication mechanisms, etc.). Overall, I believe the sponsor has identified appropriate risks of the system and mitigated these risks accordingly. The hazard analysis seems complete and I have no further concerns with this section of the submission.

Reliability Prediction

The Reliability Prediction provides a quantitative baseline for comparing product designs to the BSC CRM reliability requirements. The results of the reliability prediction serve as a resource for identifying potential improvements to the product design, manufacturing processes, user training, and component selection. The predicted total failure rate is a combination of the component failure rates using software that ties together several tools into a comprehensive reliability prediction methodology. The reliability prediction serves as an aid in ensuring the consistent delivery of reliable new products. The predicted total failure rate was a summation of

the product design failure rates, the manufacturing process failure rates, the user environment failure rates, and the component failure rates.

The sponsor has provided the following table for the overall predicted reliability for the components listed:

Jaguar 2.0 Communicator Assembly	Reliability @ 1-year	Reliability w/ 3G Dongle @ 1-year	Reliability @ 5-year	Reliability w/ 3G Dongle @ 5-year
Jaguar 2.0 MICS	98.5%	98.1%	92.8%	90.9%
Jaguar 2.0 ISM/SRD	98.6%	98.2%	93.0%	91.2%
3G Cellular Dongle	99.6%	N/A	98.0%	N/A

*REVIEWER COMMENTS: The sponsor has demonstrated that the MICS, ISM/SRD, and 3G Cellular Dongle assemblies are reliable. The methods described above seem appropriate and I do not have any concerns with these predictions. **This information is acceptable.***

Security Risk Assessment Report

The security risk assessment addresses information security risks that may result in medical risk to LATITUDE patients; privacy risks to LATITUDE patients, clinicians, or other personnel using the system; or business risk to Boston Scientific-CRM. The security risk analysis examines the sources of risk as threats and vulnerabilities, and identifies the corrective action that may reduce or eliminate a risk using mitigation(s). Risks are examined for each LATITUDE system component and for all of their interactions with each other.

This security risk assessment for the LATITUDE NXT 2.0 system release concludes that:

- Potential security risks that could result from using the LATITUDE NXT 2.0 system have been identified and documented
- The appropriateness of the mitigations for each security risk have been peer reviewed and approved
- The results of the security risk assessment have been peer reviewed and approved
- The remaining (residual) risks are acceptable when weighed against the intended benefits

The security risk assessment can be found in Exhibit 9-06: Dragon Jaguar 2.0 Security Risk Assessment Report (b)(4) TS/CCI.

REVIEWER COMMENTS: The security risk assessment is adequate. Potential security risks are identified and mitigated appropriately. This information is acceptable.

Failure Modes Effects Analysis

A Failure Mode and Effects Analysis (FMEA) is a formal and systematic method of identifying and evaluating the causes and effects of potential failure modes in components, systems,

products and processes. The sponsor has provided the FMEA in Exhibit 9-07: LATITUDE NXT 2.0 Communicator Design FMEA (b)(4) TS/CCI

*REVIEWER COMMENTS: The FMEA provided lists each potential failure mode, the severity, root cause, engineering/design controls, and verification/validation activities associated with each failure mode. This serves as a traceability matrix for the entire system. All failure modes have been traced appropriately to each of the categories listed above and have been verified and validated through electrical and mechanical testing. I have no concerns with this section of the review. I believe the sponsor has adequately identified potential failure modes and assessed them accordingly. **This information is acceptable.***

Design Validation

Boston Scientific conducted design validation testing on the system to demonstrate that it meets user needs and meets its intended use. This included System Features and Simulated Use Testing and a Usability Engineering Study.

REVIEWER COMMENTS: A human factors reviewer provided a consult for this section of the submission during the first round of review. Overall, he discovered deficiencies in the testing and recommended several deficiencies be sent to the sponsor. These deficiencies were sent in the 18 February 2014 Major Deficiency Letter and the sponsor provided responses in Amendment 1. The consultant reviewed these responses and found them acceptable. He has no further concerns with the design validation testing.

Clinical Information

The sponsor believes that a clinical study of the Wave NXT 2.0 Communicators and updated NXT Server software was not required because safety and effectiveness of the system was adequately demonstrated in non-clinical studies described in Section 9 of the submission. Additionally, conversations with FDA during previous pre-IDE discussions and through subsequent system software upgrade submissions for the LATITUDE Patient Management RF/Inductive system supported this assessment. It should be noted that the LATITUDE system does not have the capability to affect programming of the device; it has only the ability to read and record collected data.

*REVIEWER COMMENTS: I agree with the sponsor's assessment that clinical data is not required to support the changes described in this submission. **This information is acceptable.***

Post Market Clinical Follow Up

A Post Market Clinical Follow Up is not planned for the LATITUDE NXT 2.0 system software and related changes described in this submission. The sponsor has provided a Post Market Surveillance Plan for the LATITUDE NXT Patient Management System following the Post Market Surveillance Plan Procedure (b)(4) TS/CCI provided as Exhibit 12-1 of the submission. The objective of the post market surveillance plan is to describe the post market activities planned for the LATITUDE NXT Patient Management System. Activities include, but are not limited to, field performance monitoring, trend investigation, and customer surveys.

The LATITUDE Patient Management System that includes Wave and G2 Communicators, LATITUDE NXT 2.0 system software, and other associated software and accessories, has the same intended use as the existing LATITUDE System. The LATITUDE NXT system does not have the capability to affect programming of the PG devices; it has only the ability to read and record collected data. Therefore, a post market clinical study is not planned.

*REVIEWER COMMENTS: I agree with the sponsor's assessment that a post-market clinical study is not necessary. An epidemiology reviewer was assigned a consult to review this information during the first round of review. He also believes that a post-market clinical study is not necessary, and the surveillance activities listed above are adequate. **This information is acceptable.***

Conclusion and Recommendation

Overall, the sponsor has adequately addressed the deficiencies sent in the 18 February 2014 Major Deficiency Letter. One issue came up in the review of the responses regarding EMC/EMI Testing, and this was resolved through interactive review. Based on my review of the submission and the reviews of the consultants, there are no further concerns with modifications to the LATITUDE NXT Patient Management System. I recommend approval of this supplement.