**SUMMARY OF:**

**P910077/S119**
LATITUDE Wave Communicator Model 6498 and system software LATITUDE NXT Model 6460 Software Version 1.01.04 for the LATITUDE Patient Management System.

Boston Scientific Corporation
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St. Paul, MN 55112

## BACKGROUND/REASON FOR SUPPLEMENT

The 180-day PMA/S (subject file) was submitted by Boston Scientific Corporation/BSC (the company) for requesting the approval of the LATITUDE Wave Communicator Model 6498 and system software LATITUDE NXT Model 6460 Software Version 1.01.04 for the LATITUDE Patient Management System.

The reviewer does not has **any** prior communication with the company, with respect to the subject device in this PMA/S, Therefore, please contact others, who was involved for the subject device. The prior communications in the subject PMA/S are the conference calls, meetings, PRE-IDE files, etc. between the FDA and company. This review is based on the information of this PMA/S with the exception for the prior communications between the FDA and company.

## INDICATIONS FOR USE

NOTE: The company claims, "the indications for use" are unaffected by the purposed changes in this PMA/S, and are as follows:

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. There are no changes to Intended Use from the predicate LATITUDE system.

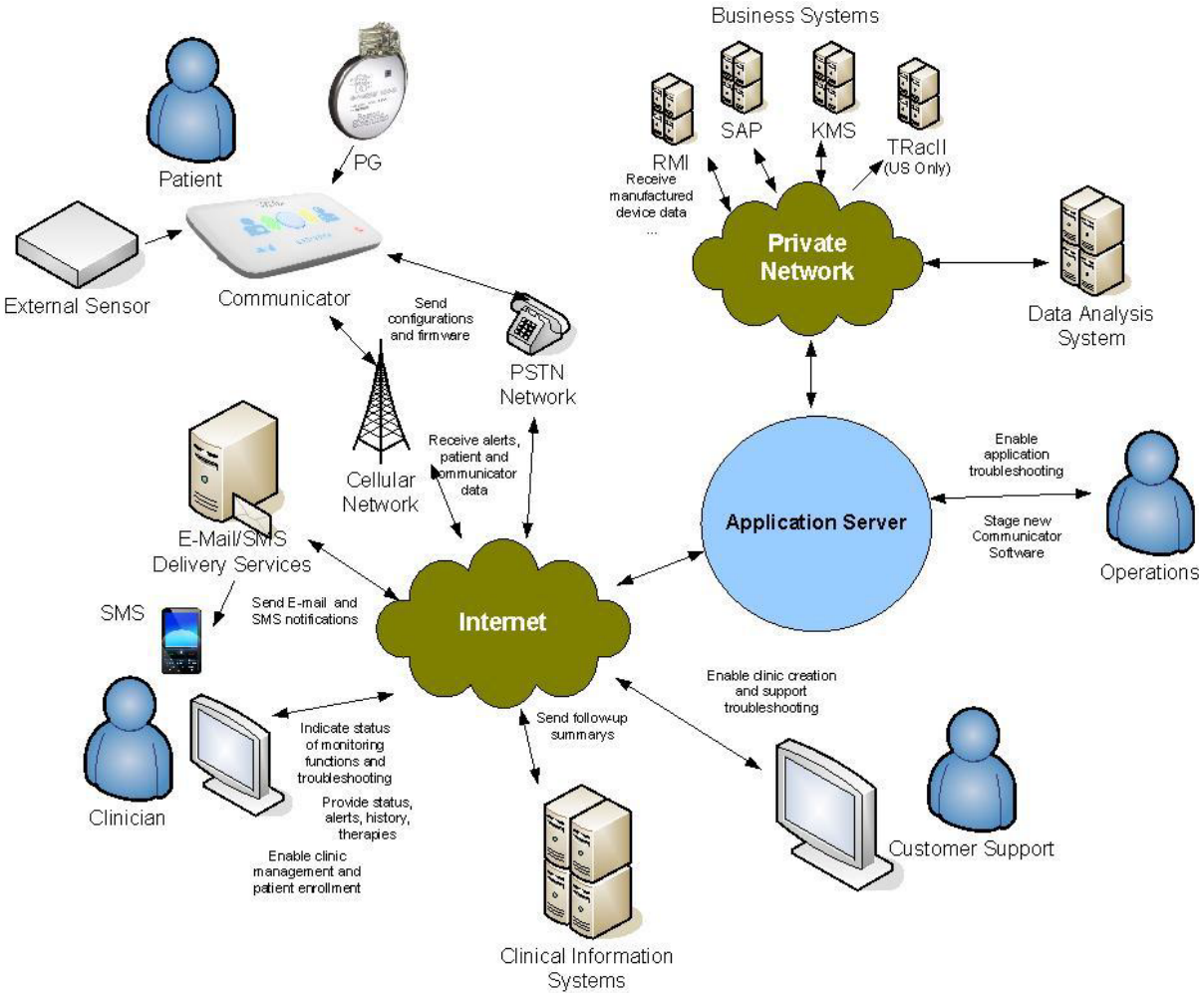
## DEVICE DESCRIPTIONS

The company claims that, the LATITUDE NXT patient management system enables physicians and other authorized health care professionals to periodically monitor patient and PG device status remotely. Use of the LATITUDE NXT system can decrease the need for routine in-office follow-up visits and enhance both patient convenience and care. The Wave Communicator portion of the system sends PG interrogation results to the LATITUDE NXT server via phone line or cellular network, to be viewed by clinicians via their PC using a web browser.

Data collected by the Wave Communicator from the implanted device (data such as battery and lead status, stored episodes, device counters and settings1) at times scheduled by the physician are combined with externally collected data from an optional weight scale and/or blood pressure monitor. By combining these internal and external measurements with

historical information, physicians can use the LATITUDE NXT system to help develop a more informed understanding of the patient's implanted device and health status. Clinicians can periodically monitor devices remotely and bring patients into the office when appropriate. It should be noted that the system is not designed to provide continuous monitoring.

**NOTE:** It appears the LATITUDE NXT patient management system contains the LATITUDE NXT system (a sub-system), and other subsystems such as the wave communicator, etc. Furthermore, it has software as well.




The company provided the following information for the terminology used in this file.

> The device trade name LATITUDE NXT is used to describe the new system software (model 6460). Within this submission, the term LATITUDE NXT is also used to describe the entire new patient management system, consisting of the new LATITUDE Wave Communicator (model 6498) and LATITUDE NXT system software (model 6460), in order to distinguish the new patient management system from the existing LATITUDE system, where appropriate, accompanying text is utilized in the submission to clarify the distinction.

(b) (4)

[redacted]

**THE SUMMARY FOR THE REVIEW**

The subject device is required to have the system testing, hardware testing, software testing, firmware testing, and environmental testing. In addition, the manufacture and QSR are required to be review by CDRH/OC. Furthermore, the labeling, and other PMA/S related information are required to be reviewed.

*CDRH/OC*, conducted the review for the manufacture (QSR) information. The GMP inspection is required. Based on the final PMA/S Amendment of the subject file, CDRH/OC clearance the inspection.

*CDRH/OSEL* conducted the consult review for the EMI/EMC, etc. (b) (4)

(b) (4)

[redacted]

**BIOCOMPATIBILITY:** N/A

**ANIMAL STUDY:** N/A

**CLINICAL DATA:** N/A

**LABELING:**

*Acceptable based on the November 2, 2012 inputs from the FDA.*

**CONCLUSION**

The company has fully addressed the deficiencies in the FDA/CRDH/ODE letter dated June 4, 2012. All the deficiencies listed in the original review are resolved.

The company has received the clearance of the GMP (QSM) from CDRH/OC for the subject file.

With above, I recommend the approval of the subject PMA/S.