**SUMMARY OF: P960040/S360 (Master File), P010012/S405**
**NG3 family of devices**
**Boston Scientific**

## EXECUTIVE SUMMARY:

The purpose of this 180-Day PMA Supplement is to request approval for hardware modifications to market-approved CRT-Ds and ICDs in the NG3 families of devices (DYNAGEN, INOGEN, and ORIGEN models).

| Family Name, PMA Number, Device Trade Name and Model Numbers | |
|---|---|
| | **Cardiac Resynchronization Therapy-Defibrillator (PMA P010012)**<br>NG3 CRT-D:<br>DYNAGEN CRT-D: G150, G151, G154<br>DYNAGEN X4 CRT-D: G156, G158<br>INOGEN CRT-D: G140, G141<br>INOGEN X4 CRT-D: G146, G148<br>ORIGEN CRT-D: G050, G051<br>ORIGEN X4 CRT-D: G056, G058 |
| | **Implantable Cardioverter Defibrillator (PMA P960040)**<br>NG3 Extended Life ICD:<br>DYNAGEN EL ICD: D150, D151, D152, D153<br>INOGEN EL ICD: D140, D141, D142, D143<br>ORIGEN EL ICD: D050, D051, D052, D053<br><br>NG2.5 MINI ICD:<br>DYNAGEN MINI ICD: D020, D021, D022, D023<br>INOGEN MINI ICD: D010, D011, D012, D013<br>ORIGEN MINI ICD: D000, D001, D002, D003 |

There are no changes to device intended use, firmware, programmers, nor are any new therapies or features being added to the devices. There are no changes to the manufacturing location of the devices. Current manufacturing locations include:

Boston Scientific Corporation
4100 Hamline Avenue North
Saint Paul, Minnesota 55112-5798 USA
FDA Establishment Registration #2124215

Boston Scientific Corporation
4100 Hamline Avenue North
Saint Paul, Minnesota 55112-5798 USA
FDA Establishment Registration #2124215

Boston Scientific Limited
Cashel Road
Clonmel
Co. Tipperary
Ireland
FDA Establishment Registration #9616693

*LEAD REVIEWER COMMENTS: The firm had initially requested both hardware and* (b)(4) *changes, which did not apply to the same devices across PMAs. PMA Staff noticed that this was improper device bundling, and BSC was contacted. As a result, BSC submitted an* (b)(4) *This review therefore only applies to the hardware/design changes for the NG3 families of devices (P010012 and 960040), and the firm wil* (b)(4) *changes as a Real Time Review.*

**DEVICE DESCRIPTION:**

Device descriptions for the NG3 family of devices are not being changed with this submission. ICDs are high energy devices that provide therapy for the treatment of ventricular tachycardia and ventricular fibrillation, abnormal rhythms that are associated with sudden cardiac death. They are compatible with pace/sense leads and cardioversion/defibrillation leads. CRT-Ds are devices that provide cardiac resynchronization therapy to treat heart failure; they can also provide ICD therapy. They accept pace/sense leads and cardioversion/defibrillation leads, using electrical stimulation on the left or both ventricles to synchronize ventricular contractions. Both types of devices communicate using RF wireless telemetry and can provide noninvasive diagnostic testing and therapy history data.

**INDICATIONS AND USAGE:**

CRT-Ds are indicated for patients with heart failure who receive stable optimal pharmacological therapy. ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation to treat life-threating ventricular arrhythmias.

**DESCRIPTION OF CHANGES (SUMMARY):**

The firm is requesting 9 hardware and 1 packaging modification to the NG3 family of CRT-Ds and ICDs:

1. Added alternate feedthrough assemblies that have specific components removed
2. Changes to hybrid assembly:
    a. Added new hybrid assemblies with new components
    b. Modified PCB and added new supplier
    c. Modified the 3-axis accelerometer
    d. Swapped LV1 and LV2 lead switches with RAR and RAT lead switches (high voltage charge module—HVCM) and added an alternate supplier for MOSFETS used in lead switches
    e. Added new version of super output module (SOM) to account for HVCM lead switches
    f. Added two new suppliers for MOSIGT
    g. Added new supplier for alternate discrete capacitors
3. Modified dump resistor and added a new supplier
4. Modified audible tone speaker design
5. Modified back liner design to accommodate new speaker and dump resistor connections
6. Modified telemetry coil design (changed insulation) and added an alternate supplier

7. Added a new supplier for (b)(4)
8. Added a new supplier for (b)(4) with modified design
9. Added (b)(4) that is internally designed and manufactured
10. Redesigned final packaging to re-size and incorporate new features

A more detailed review of each change and accompanying testing is provided below.

**FIELD ACTIONS:**

There are no current field actions issued for NG3 devices, however, the firm identified several field actions that occurred in the past and have since been addressed. Past field actions included a subset of devices displaying premature battery depletion, test anomalies that decreased product manufacturing yield, and out of range shock lead impedance alerts. There were also several cases of design issues, including weakened header bond, non-secure lead connections, and RV lead complications.

*LEAD REVIEWER COMMENTS: Past field actions were reviewed for NG3 devices. All recalls have been addressed and closed, and there are no remaining concerns that are relevant to the safety or effectiveness of the proposed changes.*

**RISK MANAGEMENT:**

BSC's safety risk management process facilitated risk analysis, evaluation, and control for these changes. A hazard analysis identified potential hazards while the safety risk management report confirmed that any risks were appropriately mitigated.

*LEAD REVIEWER COMMENTS: Results of the hazard analysis indicate that no new hazards were created or identified as a result of the proposed changes; existing hazard analysis for NG3 devices remains valid. Any concerns can be properly mitigated by component qualification and verification/validation testing of the finished device.*

**NON-CLINICAL STUDIES:**

BSC performed Ripple Effects Analysis (REA) to establish the impact of the proposed changes and to determine recommended testing.

*LEAD REVIEWER COMMENTS: REA recommended that component qualification, electrical design verification testing, and mechanical design verification testing be performed. Component qualification confirms that new and modified parts meet specification and are suitable for use. Mechanical DVT includes hermeticity, DF4/IS4 current leakage and insulation impedance using a standardized test pin, and DS4/IS4 insertion force. Electrical DVT includes chamber sensing, telemetry, electrical EMI, and coulometer calculations. Packaging DVT was not repeated for the proposed change because the new clamshell box has already been approved for Ingenio 2 devices under P030005/S113.*

**CLINICAL STUDIES:**

No new human clinical data was included to support the proposed device modifications. However, the firm did include post market data (through September 17, 2015) including total units sold and medical device reports, to support reliability of current approved device models.

*LEAD REVIEWER COMMENTS: Out of (b)(4) devices sold worldwide, there were only ( ( confirmed failures. Cumulative survival is ≥99.8% for models of sufficient sample size. In my opinion there is nothing to indicate any unusual safety or effectiveness concerns for the NG3 family of devices.*

**REVIEW OF CHANGES:**

This submission includes changes to pulse generator hardware, one packaging change, and DVT testing to support the changes. Each individual change is reviewed below.

Change #1: Filtered feedthrough assembly

This change adds alternate (b)(4) filtered feedthrough assemblies specific to IS-1 CRT-Ds and ICDs. Components such as feedthrough wires and filtering capacitors are removed from these new assemblies, since (b)(4)

**Figure 2-3: Comparison of the (b)(4) filtered feedthru assemblies.**

(b)(4)

*LEAD REVIEWER COMMENTS: Previously, IS-1 ICDs and CRT-Ds were built with IS-4 feedthrough assemblies, (b)(4) the required amount of wires and capacitors for IS-1 devices, and does not affect device functionality.*

Change #2: Hybrid assembly

Currently the same hybrid assembly is being used in both ICD and CRT-D devices. However, not all components are required for ICD device functionality. This proposed change adds new ICD and CRT-D (b)(4)

[redacted]

**Figure 2-6: Comparison of the Existing and Proposed Hybrid Assemblies**

(b)(4)

[redacted]

(b)(4)

[redacted]

The following subcomponents of the hybrid assemblies are impacted by this change: motherboard PCB, 3-axis accelerometer, high voltage charge module, super output module, and discrete capacitors.

*LEAD REVIEWER COMMENTS: Existing manufacturing programs were modified to accommodate changes to the hybrid assembly. Addtionally, there are no changes to process flow, equipment, process inputs/outputs, or acceptance activities.*

Change #3: Dump resistor

This change modifies the dump resistor (b)(4)

[redacted]

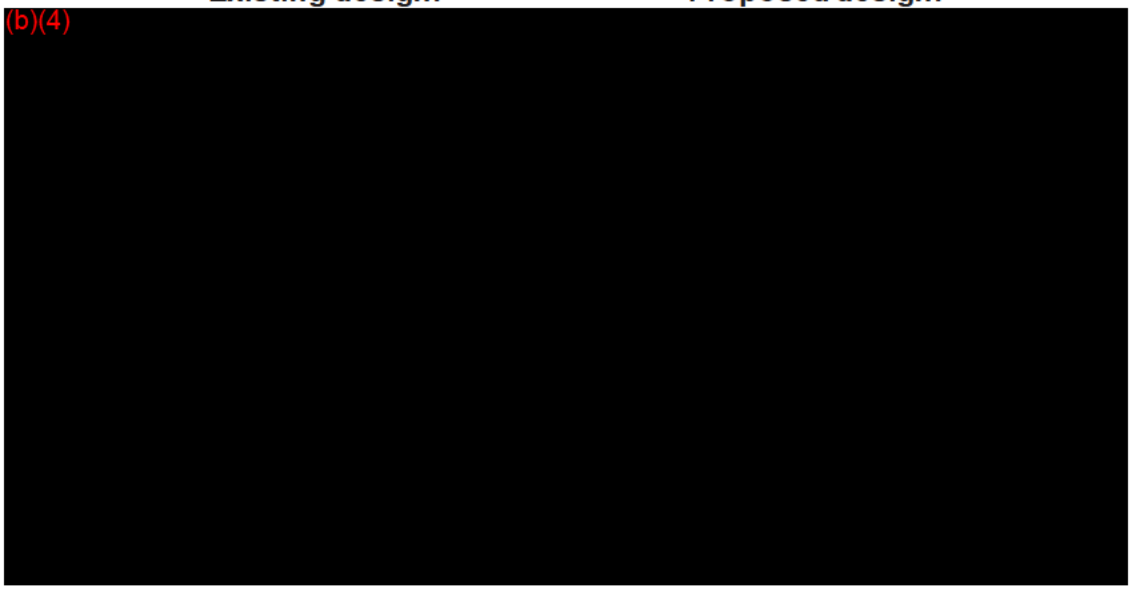
(b)(4)

[redacted]

. The dump resistor, at the command of device

software, dissipates energy from high voltage capacitors. It is currently attached (b)(4) (b) with the arm of the dump resistor attached (b)(4) . The new design will attach the dump resistor (b)(4) the dump resistor to (b)(4)

**Existing design:** **Proposed design:**

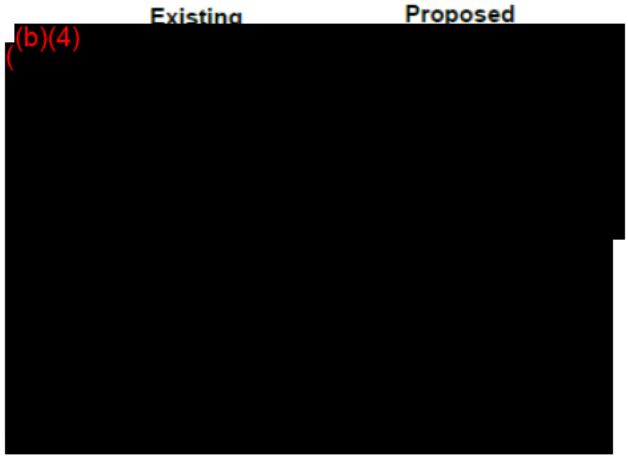



Change #4: Audible tone speaker

This change modifies the speaker design to (b)(4) . The speaker provides an audible tone to the patient to indicate specified events, if turned "On" by the physician. The new speaker has changes to physical, dimensional, and electrical specifications. It is shorter and thinner than the existing speaker, replaces the (b)(4) .

**Figure 2-12: Existing and proposed Speaker**

Existing Proposed



*LEAD REVIEWER COMMENTS: The firm provided a table (page 38) to compare existing and proposed speaker designs. The table includes a column to examine impacts of the physical, dimensional, and electrical changes, and concludes that they have no effects on device performance.*

Change #5: Back liner

A new back liner was designed to accommodate the new speaker and dump resistor connections (Changes #3 and #4); it will be used with the existing front liner. This change does not affect device functionality.

**Figure 2-13: Existing and proposed back liner**

(b)(4)

Change #6: Telemetry coil

The telemetry coil, which consists of a (b)(4) (b)(4) by which the device and programmer can communicate through a telemetry wand. While the (b)(4) To reduce cost, modifications are being made to telemetry coil insulation on (b)(4) (b)(4)

(b)(4)

Change #7: PG case halves

The external PG case currently consists of two (b)(4) case halves that are (b)(4) (b)(4). It houses the internal electronic circuit, battery, HV capacitor. A new supplier of PG case halves is being added (b)(4)

*LEAD REVIEWER COMMENTS: The firm states that the surface finish of new incoming case halves will (b)(4) . However, the final device surface finish is unchanged due to the device (b)(4) at BSC. Incoming surface finish is not a design output specification and does not affect the function of the case halves or device, therefore, I have no concerns with this modification.*

Change #8: PG anchor post

Two anchor posts (b)(4) to the PG external case to provide mechanical attachment of the header to the can. (b)(4) the manufacturing process until it is (b)(4) . A change is being made to the shape of the barb on the bottom of the PG anchor post flange, and a new supplier is being added.

**Figure 2-14: Existing and Proposed Anchor Post**


*LEAD REVIEWER COMMENTS: While the shape of the barb is being changed, the anchor plug flange (which is the (b)(4) ), remains unchanged. I have no concerns with this modification.*

Change #9: PG (b)(4) IS4/DF4 outer sleeve

This change requests vertical integration of the IS4/DF4 outer sleeve, which is currently purchased from a supplier (b)(4) . The BSC manufactured component (b)(4) that is (b)(4) into the finished device header. Because of the new adhesion method, BSC is changing the materials, axial length, and outside diameter of the outer sleeve.

**Figure 2-15: Header cross-section showing the existing bonded IS4/DF4 sleeve and the proposed (b)(4) IS4/DF4 sleeve**


Change #10: Common box/final packaging

Currently, Brady and Tachy products use different clamshell box designs. New packaging was designed so that both Brady and Tachy products can utilize a "common box" design (b)(4) (b)(4) . The NG3 packaging system consists of a double sterile barrier, with (b)(4) . Each tray is sealed with a (b)(4) . Sterile trays are placed in a (b)(4) .

**Figure 2-17: Existing US Configuration—NG3 Box Interior and Sterile Tray with Literature Installation**

**Figure 2-19: Proposed US Configuration—NG3 Box Interior and Sterile Tray with Literature Installation**

(b)(4)

*LEAD REVIEWER COMMENTS: An identical clamshell box was previously approved for Ingenio 2 devices under P030005/S113. I confirmed that this design passed packaging DVT and was previously approved by FDA; I have no further concerns.*

***Additional reviewer comments:*** *All changes met acceptance criteria for component qualification, particularly for new suppliers that were being added. Each change was supported by mechanical and electrical design verification/validation testing, as needed, on the finished sterilized devices. There were no test failures. Sample sizes were selected to achieve required confidence and reliability intervals, as determined by level of risk. I met with Senior Manufacturing Reviewer Jessica Paulsen on December 10, 2015 to discuss these changes, and no concerns were identified regarding safety or effectiveness of any singular change, or with the final device.*

**515A PEDIATRIC DEVICE USE INFORMATION:**

The firm has provided a summary of available data regarding pediatric subpopulations at risk for life threatening VTs, including those that may benefit from ICD, CRT-D, or S-ICD devices. This information is required per Section 515A of the FD&C Act and is only included for informational purposes—device labeling related to pediatric subpopulations is not being proposed nor included in this submission.

*LEAD REVIEWER COMMENTS: The firm's summary states that fewer than 1% of all ICDs are implanted in pediatric patients, and thus the evidence documenting risks and benefits is small compared to the adult population. There are currently no accepted guideline recommendations for CRT-D implantation in pediatric patients. I have no concerns with this section of the review, as Medtronic is not intending for this device to be used in pediatric subpopulations.*

**DEFICIENCIES:**
N/A

**CONCLUSION:**
The firm has adequately supported each hardware/design and packaging change with component qualification, as well as mechanical and electrical design verification/validation testing on the finished device. There were no test failures and nothing to indicate potential concerns regarding device safety and effectiveness. **Approval i**s recommended for this supplement.

**ATTACHMENTS:**
N/A