SUMMARY OF:

P030005/S92 and D970003/S143
Ingenio Family of Devices

P030005/S92
Intua Models V272, V273

D970003/S143
Vitalio Models K272, K273, K274; and
Formio Model K278

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BACKGROUND/REASON FOR SUPPLEMENT

The 180-day PMA/S (subject file) was submitted by Boston Scientific Corporation/BSC (the company) dated October 25, 2012, requesting the approval for the above referenced devices (the subject device). Furthermore, the subject file contains all the modifications as stated in a approved PMA/S, P030005/S88 and D970003/S140.

The modifications are:

The new modification:

The only feature new to VITALIO, FORMIO, and INTUA is Right Atrial Autothreshold (RAAT), which is designed to dynamically adjust the atrial pacing voltage to ensure capture of the atrium by setting the pacing voltage to a 2X safety margin. The company has provided the clinical data for this. The FDA clinical review indicates this is acceptable.

The old modifications (based on P030005/S88 and D970003/S140), under review:

(b)(4) Trade Secret

The subject device for the Ingenio platform includes the single-chamber (SR), dual-chamber (DR), and the CRT-P devices. Pacemaker devices included in this submission will be marketed

under the name VITALIO™ and FORMIO™, and CRT-P devices will be marketed under the name INTUA™. All devices in this family provide brady pacing therapy and radio frequency (RF) communication capability. INTUA also provides biventricular (resynchronization) pacing.

All features included in the approved lower tier Ingenio devices (INGENIO and ADVANTIO pacemakers [*D970003/S132*] and INVIVE CRT-P [*P030005/S079*]*; approved May 2012*) were transferred to VITALIO, FORMIO, and INTUA. The only feature new to VITALIO, FORMIO, and INTUA is Right Atrial Autothreshold (RAAT), which is designed to dynamically adjust the atrial pacing voltage to ensure capture of the atrium by setting the pacing voltage to a 2X safety margin. Heart failure (HF) diagnostics currently available in approved INVIVE lower tier CRT-P devices were also added to FORMIO pacemakers to allow for consistency across product lines. All other diagnostic, data management, and other basic operating features for the Ingenio platform are identical (irrespective of model). No changes were made to lower tier features for incorporation into these new upper tier models. Also, the subject file contains the modification of the P030005/S88 and D970003/S140.

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:

PACEMAKER INDICATIONS

INGENIO and ADVANTIO PG indications remain unchanged from the predecessor (ALTRUA) and are as follows:

INGENIO and ADVANTIO pacemakers are indicated for treatment of:

Symptomatic paroxysmal or permanent second- or third-degree AV block;

Symptomatic bilateral bundle branch block;

Symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders (e.g., sinus bradycardia, sinus arrest, sinoatrial [SA] block);

Bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias;

Neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes;

Adaptive-rate pacing is indicated for patients who may benefit from increased pacing rates concurrent with increases in MV and/or level of physical activity;

Dual-chamber PGs and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony.

Dual-chamber modes are specifically indicated for treatment of the following:

Conduction disorders that require restoration of AV synchrony, including varying degrees of AV block;

VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm.

CRT-P INDICATIONS

Indications for use for the INVIVE cardiac resynchronization therapy with pacemaker (CRT-P) remain unchanged from the predecessor RENEWAL TR device and are as follows:

Boston Scientific cardiac resynchronization pacemakers (CRT-Ps) are indicated for patients with moderate to severe heart failure (NYHA III/IV) including left ventricular dysfunction (ejection fraction<35%).and QRS duration >120 ms and remain symptomatic despite stable, optimal pharmacological therapy (OPT) for heart failure.

Atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony.

Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with increases in physical activity.

DEVICE DESCRIPTIONS

The following are the modifications for the subject device:

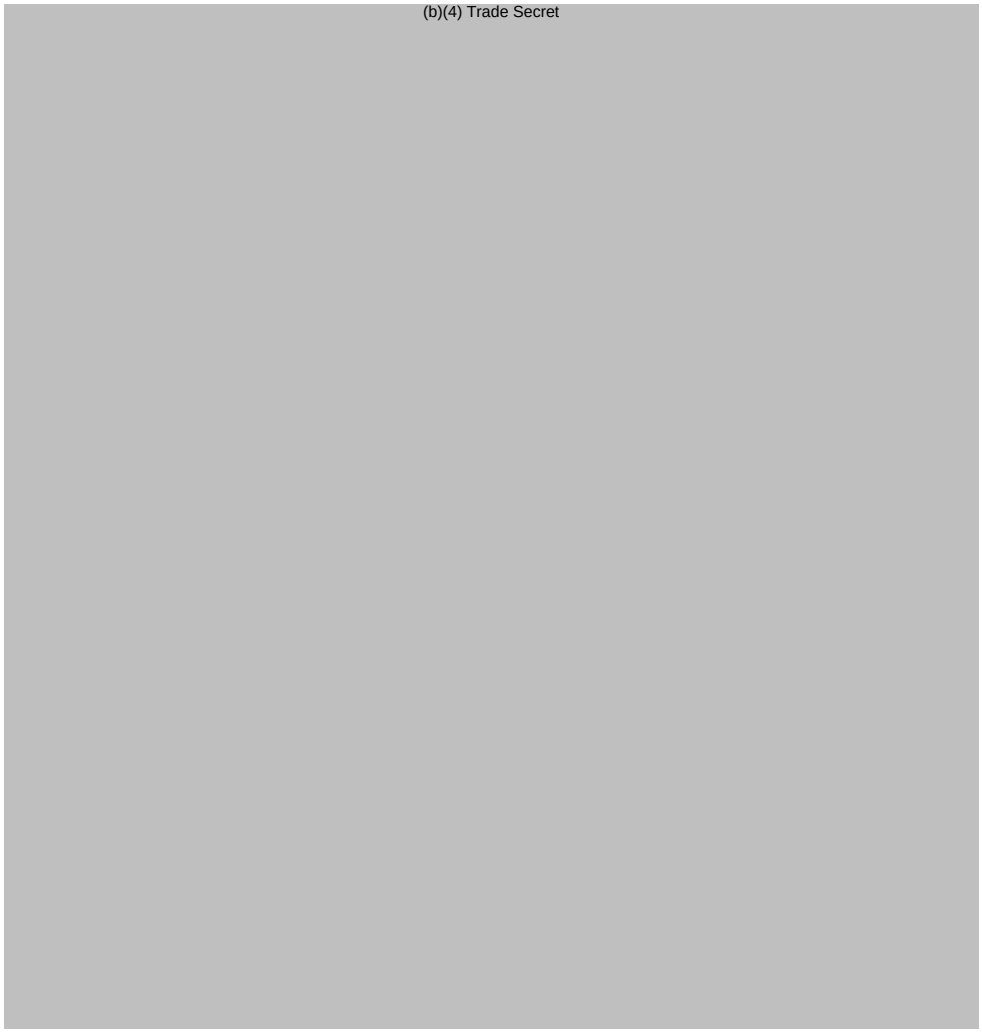
The new modification:

The only feature new to VITALIO, FORMIO, and INTUA is Right Atrial Autothreshold (RAAT), which is designed to dynamically adjust the atrial pacing voltage to ensure capture of the atrium by setting the pacing voltage to a 2X safety margin. The company has provided the clinical data for this. The FDA clinical review indicates this is acceptable.

The old modifications, (P030005/S88, etc.)

(b)(4) Trade Secret

(b)(4) Trade Secret



Mixed Mode Integrated Circuit (MMIC) – Modified the electro-static discharge (ESD) clamp circuits located on (b)(4) Trade Secret This change improves component reliability without changing the combined voltage of the circuit.

Surge Suppressor and Second Source Surge Suppressor – Upgraded the surge suppressor to one with higher RF threshold performance. Added an alternate supplier for the upgraded surge suppressor component.

Second Source Ceramic Capacitor – Added an alternate supplier for the ceramic capacitor component.

THE SUMMARY FOR THE REVIEW

The company performed design verification (DVT) and design validation testing, safety testing, and analysis to demonstrate that the system incorporating the device and manufacturing changes proposed in the subject file. Then company claims the design validation demonstrated that the system conforms to user needs and intended uses; the design verification demonstrated that all device-level requirements are met. Safety testing and analysis were conducted to identify potential hazards and their causes, and to take appropriate actions to minimize patient and user risk prior to product market release.

The company claims, during the development of the device and manufacturing changes proposed in the subject file, evaluations were completed to ensure that any changes to the devices that were made following evaluations or testing included in the original Ingenio submission (INGENIO and ADVANTIO pacemakers and INVIVE CRT-P did not impact the original testing that had been completed in support of that submission. Changes were evaluated on a case-by-case basis to determine if any possible additional testing was necessary to verify that the device continued to meet design requirements after the change.

The company provided the above process and the test reports for the modifications of the subject device. For example, the System requirements, the Validation and Verification Testing, the Ripple Effect Analysis.

Design verification testing is performed to demonstrate that all device-level requirements met the System Requirements (Rev W) (005245). The verification testing encompasses of the following: SDVT, PG EDVT, alternate component EDVT, PG MDVT, header MDVT, alternate component / supplier MDVT, packaging SDVT, PG SW DVT, highly accelerated life testing (HALT), and Model 2869 PRM SW DVT. Based on the test results in this file, it is acceptable.

The company also conducted the hazard analysis, the Hazard Analysis; and the Safety Risk Management Process, those information addressed the safety management for the subject device, it is acceptable.

The company has conducted the sterilization assessment for the subject device,

BIOCOMPATIBILITY: N/A

ANIMAL STUDY: N/A

CLINICAL DATA: b (By the FDA Clinician)

Based on the final clinical review, the clinical issues have fully resolved. Final conclusion of the clinical review is the FDA would like to see the labeling be modified, the company agreed, and modified the labeling.

The following is the summary of the clinical review based on the information is the subject file:

The subject company proposes adding (b)(4) Trade Secret They are currently available in approved INVIVE lower tier CRT-P devices and would be added to FORMIO pacemakers (reason, per firm: “allow for consistency across product lines”). These (b)(4) Trade Secret trend variability in R-R intervals over time including:

- Heart Rate variability (HRV) Plot
- HRV Footprint trend
- Heart rate trend
- SDANN trend (Standard Deviation of Averaged Normal R to R intervals)
- Autonomic Balance Monitor (ABM) trend.

The following is the company’s response to the above FDA concern:

(b)(4) Trade Secret

Based on the response from the company, FDA inform the the following concerns to the company:

- The firm clearly states that (b)(4) Trade Secret I agree with the firm that the potential for the measures to create a public health hazard is small. However the term (b)(4) Trade Secret appears inappropriate from a clinical standpoint and therefore likely to cause confusion. (b)(4) Trade Secret

  As outlined in 21 CFR Part 801 Section 502 misleading or false device labels are prohibited (considered misbranded) and considered deceptive if they create or lead to a false impression in the mind of the reader. I believe the use of the name (b)(4) Trade Secret for this feature is misleading and false, according to FDA regulations.

Finally, To remedy this problem the firm should rename the measures (feature) in labeling and on the programmer. Based on review of the subject file (the original PMA Supplement and the Amendment) I (FDA Clinician) believe that a descriptive name for the measures is acceptable and, I believe, it could be approved for use under a descriptive name (without reference to heart failure) in all of the proposed devices.

LABELING:

The company has provided the draft version of the labeling in the subject file, and will be updated to reflect the final outcome of the clinical review.

CONCLUSION

Based on the information in this file, the company has fully addressed the manufacture issues, and the clinical issue (labeling) of the subject PMA/S.