



**SUMMARY of P030005/S79 & D970003/S132  
Ingenio Family of Devices  
Invive Models V172, V173  
Ingenio Models K172, K173, K174  
Advantio Models K62, K63, and K64  
Programmer 2869 Application Software version 1.07  
Boston Scientific Corporation**

**BACKGROUND**

The 180-day PMA/S (subject file) was submitted by Boston Scientific Corporation/BSC (the company) dated July 12, 2011, requesting the approval for the above referenced devices (the subject device). The subject device for the Ingenio platform includes the single-chamber (SR), dual-chamber (DR), and the CRT-P devices.

INGENIO and ADVANTIO Pacemakers have a small, thin, physiologic shape that minimizes pocket size and may minimize device migration. INGENIO and ADVANTIO pacemakers provide bradycardia pacing, including adaptive rate features, to detect and treat bradyarrhythmias and to provide cardiac rate support after defibrillation therapy.

The INVIVE CRT-P device also has a small, thin, and physiologic shape that minimizes pocket size, and is designed to minimize device migration. INVIVE provides cardiac resynchronization therapy (CRT), which treats heart failure by resynchronizing ventricular contractions through biventricular electrical stimulation, and bradycardia pacing, including adaptive rate features.

**PRM System**

INGENIO and ADVANTIO Pacemakers; and INVIVE CRT-P will be the first brady devices with wandless RF communication capability. They can be used only with the ZOOM LATITUDE Programming System, which is the external portion of the PG system and includes:

- Model 3120 PRM;
- Model 2869 ZOOMVIEW Software Application (PRM Software); and
- Model 6577 Accessory Telemetry Wand

The company updated the application software in the PMA/S Amendment.

## **INDICATIONS FOR USE**

NOTE: The company claims, “the indications for use” are unaffected by the proposed 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**

INGENIO and ADVANTIO Pacemakers provide pacing for the treatment or prevention of bradycardia. Both model families consist of multiprogrammable devices available in either dual-chamber or single-chamber models, offering adaptive-rate therapy as well as various levels of therapeutic and diagnostic functionality. All models conform to the IS-1 standard. All models have the ability to communicate the distance telemetry via radio frequency (RF). INGENIO 170 models have the same basic feature set/functionality as the ADVANTIO 60 series, plus additional features, including Dynamic PVARP, Respiratory Rate Trend and RYTHMIQ.

INVIVE CRT-Ps are designed to provide cardiac resynchronization therapy by providing biventricular electrical stimulation to synchronize the right and left ventricular contractions. The device also provides adaptive-rate bradycardia therapy and the ability to communicate the distance telemetry via radio frequency (RF).

The INVIVE CRT-P, along with a commercially available coronary venous pace/sense lead, a commercially available transvenous atrial pace/sense lead, and a commercially available right ventricular pace/sense lead constitute the implantable portion of the CRT-P system. The CRT-P has a Trilumen lead connector. The atrial and right ventricular lead barrels conform to the IS-1 standard, and the left ventricular lead barrel conforms to the IS-1 standard or LV-1 port, depending on the model. Pacing and sensing are independently programmable to bipolar or unipolar in the atrium, and a single programmable ventricular channel is used for bipolar or unipolar pacing and sensing in the ventricles.

The ZOOM Programming System, which includes the Model 3120 Programmer/Recorder/Monitor (PRM), the Model 2869 Software Application, and an accessory telemetry wand, constitutes the external portion of the Ingenio system. The external components allow interrogation and programming of the pulse generator as well as access to the device's diagnostic features. The Ingenio system can be programmed to provide a variety of therapy options. It also can provide noninvasive diagnostic testing and therapy history data.

Based on the information in PMA/S Amendment 02, the following features were modified for the subject device. Those are: The AGC can be selected ON/OFF instead of automatic be ON.

## SUMMARY FOR THE MAJOR DEVICE CHANGES

### **Electrical Hardware:**

The Ingenio electrical hardware can be considered a subset of the electrical hardware found on market approved devices, COGNIS/TELIGEN (C/T), since Ingenio is a low-voltage brady platform. The “core” hardware used on Ingenio is substantially equivalent to the core hardware used on the C/T platform. For example, the microprocessor / memory IC used on Ingenio is identical to the one used on C/T. Likewise, the RF module used on Ingenio is the same module that is used for C/T.

The main hardware differences between the two platforms are associated with the analog IC and the hybrid-level support components. The hardware implemented on the analog IC consists of a collection of common circuit “assets” that are designed to support both the brady and fully-featured tachy platforms. In this manner, the analog IC circuitry used on Ingenio is essentially the same as the analog IC circuitry used on C/T, and is capable of supporting tachy as well as brady functions, with the tachy capabilities being permanently disabled. In addition to the above, the subject device hardware contains the new ROMware (firmware/hardware) for the subject device; the hardware modifications such as the Error Correction C. (ECC) feature, etc. The supplier for this IC is ON Semiconductor. Based on the information from one of the company’s e-mail (dated 2/11/2012, the analog signals also including the telemetry communication.

*Summary: The company claims, this is the first generation of the common hardware platform with the common ROMware between the low voltage system (pacemaker and CRT-P) and high voltage system (ICD and CRT-D).*

### **PG Mechanical:**

The Mechanical configuration of Ingenio is similar to C/T construction in that it is made from the same basic set of materials (e.g. Titanium cans and Tecothane Headers) and therefore has many similar design and processing aspects. Difference include the incorporation of the RF Antenna into the header, removal of the high voltage capacitors thus affecting the device form factor, and use of a rigid printed circuit board. A robust header attachment design has been implemented for all Ingenio platform devices.

### **Pulse Generator (PG) Software (firmware)**

The Ingenio pulse generator software (PG SW) uses the reference architecture developed for the COGNIS/TELIGEN PG. It is a platform architecture designed to support both Tachy and Brady product lines. The architecture provides the top-down decomposition of the PG software into functional components and defines the interfaces and interconnections between these components. This architecture uses the Product Line Engineering (PLE) methodology, which allowed a set of features to be easily selected or removed for a particular product from a common features repository. From a PG SW design perspective, all core PG SW infrastructure is reused directly from the COGNIS/TELIGEN platform.

*NOTE 1: The subject file contains the ‘almost common’ hardware platform with the uniquely differences of the ROMware between the subject device and the market approved devices, COGNIS/TELIGEN devices. In addition, the application software for the*

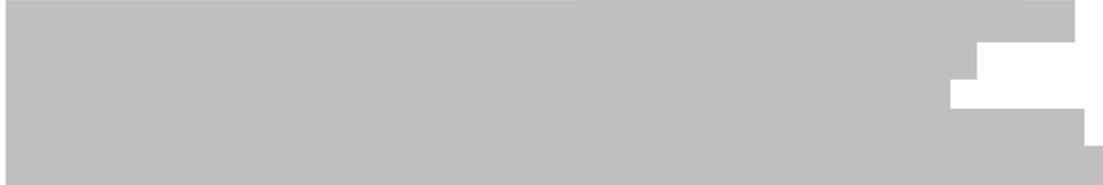
*programmer is updated for the subject implantable devices. Based on the information provided by the company to FDA via e-mails, the key point shall be focus on the PCB from ON Semiconductor since this PCB contains microprocessor, RAMware, etc.*

The following is the summary of the information submitted in the original PMA/S file. Those are:

- The executive summary with the submission overview;
- Indication for use statements for pacemaker and CRT-P;
- Device descriptions for pacemaker and CRT-P;
- Major device changes, platform, hardware (and the comparison), features, firmware (and error detection move to hardware), etc.,
- Top level system functions such as the header, external case, batteries (two battery types), assembly, boards, liners, etc. *NOTE, the company did not provide any IC information;*
- Level of concerns;
- Software (application software for the programmer);
- Manufacture information with the major manufacturing changes, and the sites;
- Quality System Regulation (QSR) information;
- Listed the performance standards in exhibit 3.1;
- System evaluation plan/report;
- Device verification testing;
- System design verification testing (SDVT);
- Electrical Design verification testing for Battery Management, Device Environment – Electromagnetic Interference (EMI), Additional Electrical Testing;
- Mechanical Design Verification tests (MDVT);
- PG software design verification tests;
- Animal Study;
- Biocompatibility studies;
- Sterilization assessment;
- System risk management, hazard analysis and safety management;
- Reliability Prediction;
- Failure Modes and Effects Analysis (FMEA);
- Pre-IDE information;
- Published information and bibliography;
- Product reliability data for the approved devices with the trend reports;
- Labeling;
- Pediatric Subpopulation Information; and
- Environment assessment;

After completed the review of the information in the PMA/S, with the comments from the above consult reviewers, the following is the summary:

This PMA/S referenced a Master File, MAF (b) (4)



Volume 1 of the original subject file contains general PMA/S required information such as the description of the device, the modifications, the device features, manufacture information, some software information.

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Beside the manufacture information in Volume 3, it contains the ripple effect analysis reports top level testing concepts/strategies such as plans, test designs, etc.

Volumes 4, 5, 6, 7, and 8: the test reports, specifications and requirements, analysis, the animal study, etc. Volume 4 contains hardware verification test reports; Volume 5 contains the system requirements. Battery information and the software test reports in Volume 7; System features test report in Volume 8;

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Volume 9 contains hazard analysis report.

Volume 10 contains the literature review, reliability predication, failure modes and affects analysis, component testing, trend reports (from ex 7-2 to ex. 7-05), and labeling.

Volume 11 contains labeling information.

#### **BIOCOMPATIBILITY**

Based on the e-mail from the company, no additional materials in the subject file. Therefore, this item is closed.

#### **CLINICAL DATA**

N/A

#### **CONCLUSION**

Based on the information in the file, the company has provided the appropriate data to demonstrate the subject device is safe and effective.