SUMMARY OF:

P030005/S88 and D970003/S140
Ingenio Family of Devices

P030005/S88
Invive Models V172, V173

D970003/S140
Ingenio Models K172, K173, K174; and
Advantio Models K62, K63, and K64

Boston Scientific Corporation
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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 September 14, 2012, requesting the approval for the above referenced devices (the subject device). The modifications are:

1. Overmolded Header;
2. Mixed Mode Integrated Circuit (MMIC)
3. Surge Suppressor and Second Source Surge Suppressor
4. Second Source Ceramic Capacitor

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.

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:

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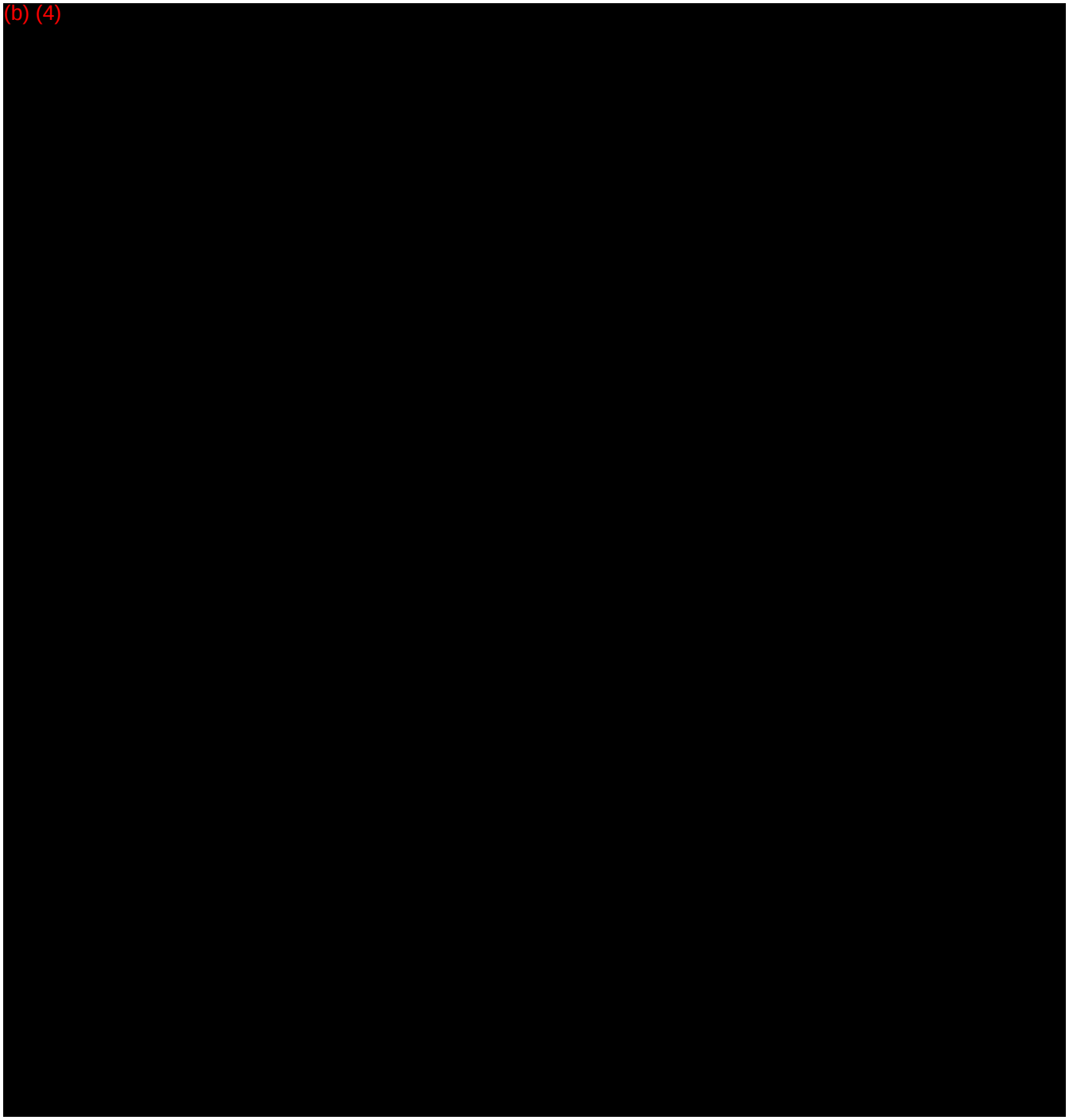

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THE SUMMARY FOR THE REVIEW

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BIOCOMPATIBILITY:

Based on the modifications in the header, the company conducted a number of the tests which are related to the biocompatibility, and claiming all the tests are passed and it is acceptable for implant. In addition, the company provided the certifications for the new materials. Furthermore, the company claims, it has licensed the technology from the manufacturer of the new materials. Based on the information is the subject file, it is acceptable.

ANIMAL STUDY: N/A

CLINICAL DATA: N/A

LABELING:

The company has provided the labeling for this file, and it is acceptable. Please note the major items were changed, those are device longevity, and the items associated with the 'future' (b) (4) Patient Management System.

CONCLUSION

Based on the information in this file, the company addressed the manufacture issues, and CDRH/OC accepted it for the approval of this PMA/S.