Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

DATE: March 5, 2013

SUBJECT: Summary of P110042-S002 PMA Supplement

Cameron Health – New sources and formulations for battery cell materials

OVERALL RECOMMENDATION

Based on my review of the submission, **I recommend approval of the submission**.

PURPOSE OF SUBMISSION

The firm submitted this PMA supplement to request approval for new sources and formulations for battery cell materials. Specifically, the firm is requesting a change to the formulations of (b) and (b). The modifications and supporting testing are described in greater detail below.

A request for Real Time Review was submitted on October 16, 2012, and rejected on October 22, 2012. The request was rejected because the scope of the review would exceed what could be covered in a single conference call.

DEVICE DESCRIPTION

The device is subcutaneous implantable defibrillator system. The battery is a component of the SQ-RX Pulse Generator, Model 1010. The original PMA for the system was approved on September 28, 2012, following a meeting of the cardiovascular devices advisory panel in April 2012.

INDICATIONS FOR USE

There were no changes to the indications for use.

HARDWARE TESTING

(b) (4)

(b) (4)

(b) (4) Material Supplier Changes

Material	***Supplier/Product Description***	
	Original	***New***
(b) (4)		

(b) (4)

(b) (4)

Proposed Process Specification Changes

	Procurement Specification (b) (4))		***Hardware Specification*** (b) (4)	
Specification	***From***	***To***	***From***	***To***
(b) (4)				

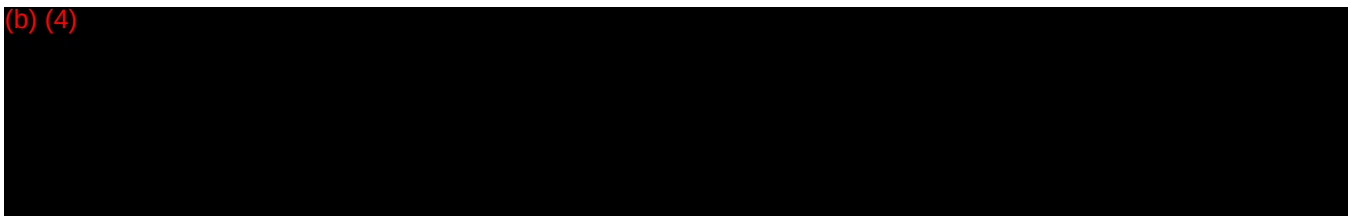
(b) (4)

Supporting Data

(b) (4)

Device Longevity and Charging Time

(b) (4)



(b) (4)

[redacted]

Summary

I reviewed the firm's summary of the changes as well as all of the supporting documentation. I believe that the supplier and firm have conducted the appropriate testing and that these modifications will not adversely impact the safety or effectiveness of the device.

EMC / EMI TESTING

There were no changes relevant to this issue. This section is not applicable to this submission.

SOFTWARE VERIFICATION AND VALIDATION

There were no changes relevant to this issue. This section is not applicable to this submission.

BIOCOMPATIBILITY

There were no changes relevant to this issue. This section is not applicable to this submission.

CLINICAL

There were no changes relevant to this issue. This section is not applicable to this submission.

STATISTICAL

There were no changes relevant to this issue. This section is not applicable to this submission.

ANIMAL TESTING

There were no changes relevant to this issue. This section is not applicable to this submission.

PACKAGING, STERILIZATION, AND SHELF-LIFE

There were no changes relevant to this issue. This section is not applicable to this submission.

LABELING

There were no changes relevant to this issue. This section is not applicable to this submission.

Specifically, there are no changes to the overall performance or longevity of the pulse generator as a result of these changes.

POST-MARKET REQUIREMENTS

There were no changes relevant to this issue. This section is not applicable to this submission.

INTERACTIONS WITH OTHER FDA PERSONNEL AND SPONSOR

The primary contact for the sponsor is Esther Saltz (949-940-4004, Esther.Saltz@bsci.com).

February 15, 2013

I contacted the firm to request confirmation that these modifications to the battery materials are not related to any previous or current field events, recalls, or safety alerts. The firm provided the requested confirmation via email:

> **From:** Saltz, Esther [Esther.Saltz@bsci.com]
> **Sent:** Friday, February 15, 2013 1:55 PM
> **To:** Skodacek, Ken
> **Subject:** Review of P110042/S002
> Mr. Skodacek,
> Thank you for your review of P110042/S002. Per our phone call this morning, I am sending this message is to confirm that the changes associated with P110042/S002 are driven by material obsolescence only. The changes are not related to field events. Additionally, these changes are unrelated to previous battery issues encountered during the IDE study.
> Please do not hesitate to contact me if you require additional clarification or have any additional questions.
> Best regards,
> Esther
> **Esther Saltz**
> Manager, Regulatory Affairs
> **Boston Scientific Corporation**
> 905 Calle Amanecer, Ste. 300
> San Clemente, CA 92673, USA