



MEMORANDUM

SUMMARY OF:

P960040/S270  
P010012/S300  
Enhancements and modifications to Cognis, Teligen, Incepta, Energen, and  
Punctua models  
*Boston Scientific*

BACKGROUND

Boston Scientific is requesting approval to enhance and modify the following devices:

- COGNIS Models N118/N119 (*P010012/S165, approved May 8, 2008*)
- TELIGEN Models E102/E110 (*P960040/S155, approved May 8, 2008*)
- INCEPTA CRT-D, ENERGEN CRT-D, PUNCTUA CRT-D Models N160, N161, N164, N140, N141, N050, N051 (*P010012/S255, approved November 17, 2011*)
- INCEPTA ICD, ENERGEN ICD and PUNCTUA ICD Models E160, E161, E162, E163, E140, E141, E142, E143, E050, E051, E052, E053 (*P960040/S235, approved November 17, 2011*)

Modifications to these market approved devices include:

- Software changes made to create Programmer (PRM) software (SW) Model 2868  
(b) (4)
- Software changes made to create INCEPTA, ENERGEN and PUNCTUA Pulse Generator (PG) Firmware (FW) (b) (4)
- Software changes made to create COGNIS and TELIGEN PG FW (b) (4)
- Hardware changes made to the mixed-mode integrated circuit (MMIC) and battery
- Labeling changes to the Reference Guides and Physician Technical Manuals

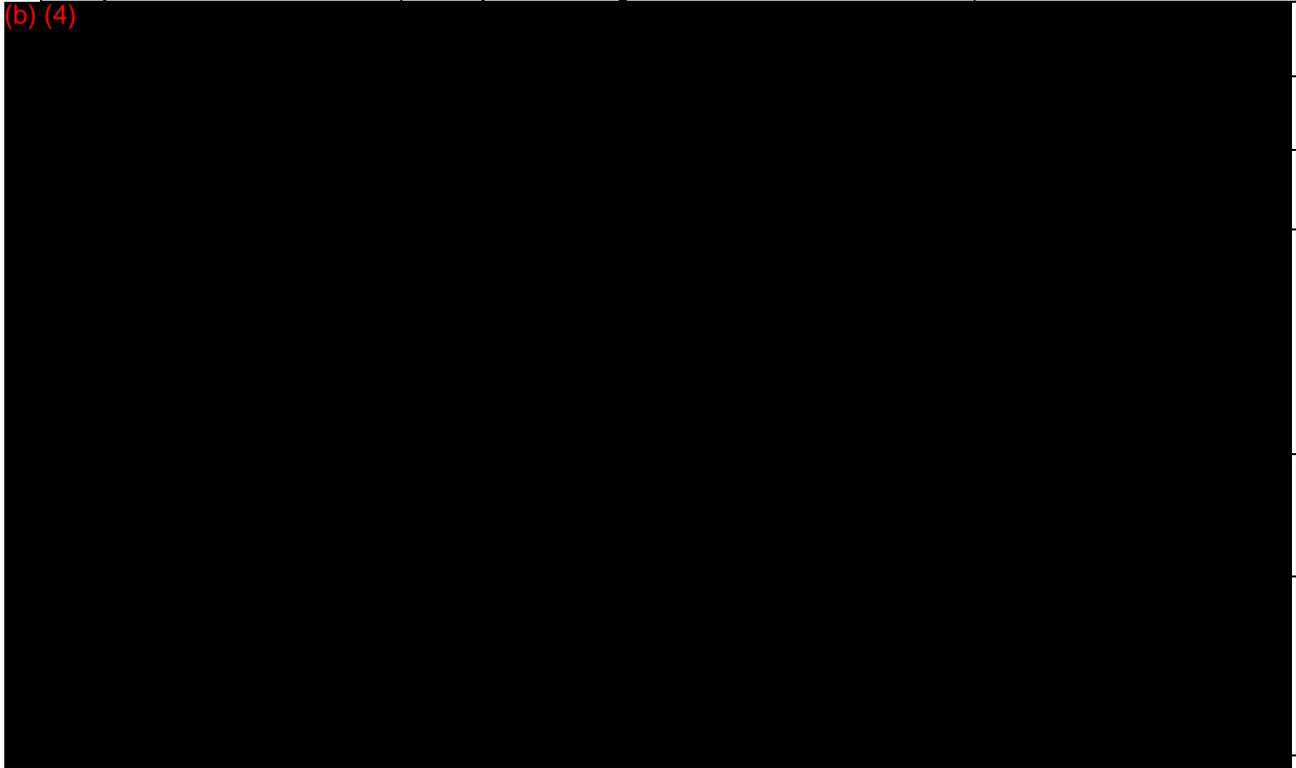
INDICATIONS FOR USE

The indications, contraindications and Alternate Practices and Procedures for the modified CRT-D and ICD devices remain the same. These indications, contraindications and Alternate Practices and Procedures were restated in the submission for reference.

DEVICE DESCRIPTION AND CHANGE DESCRIPTION

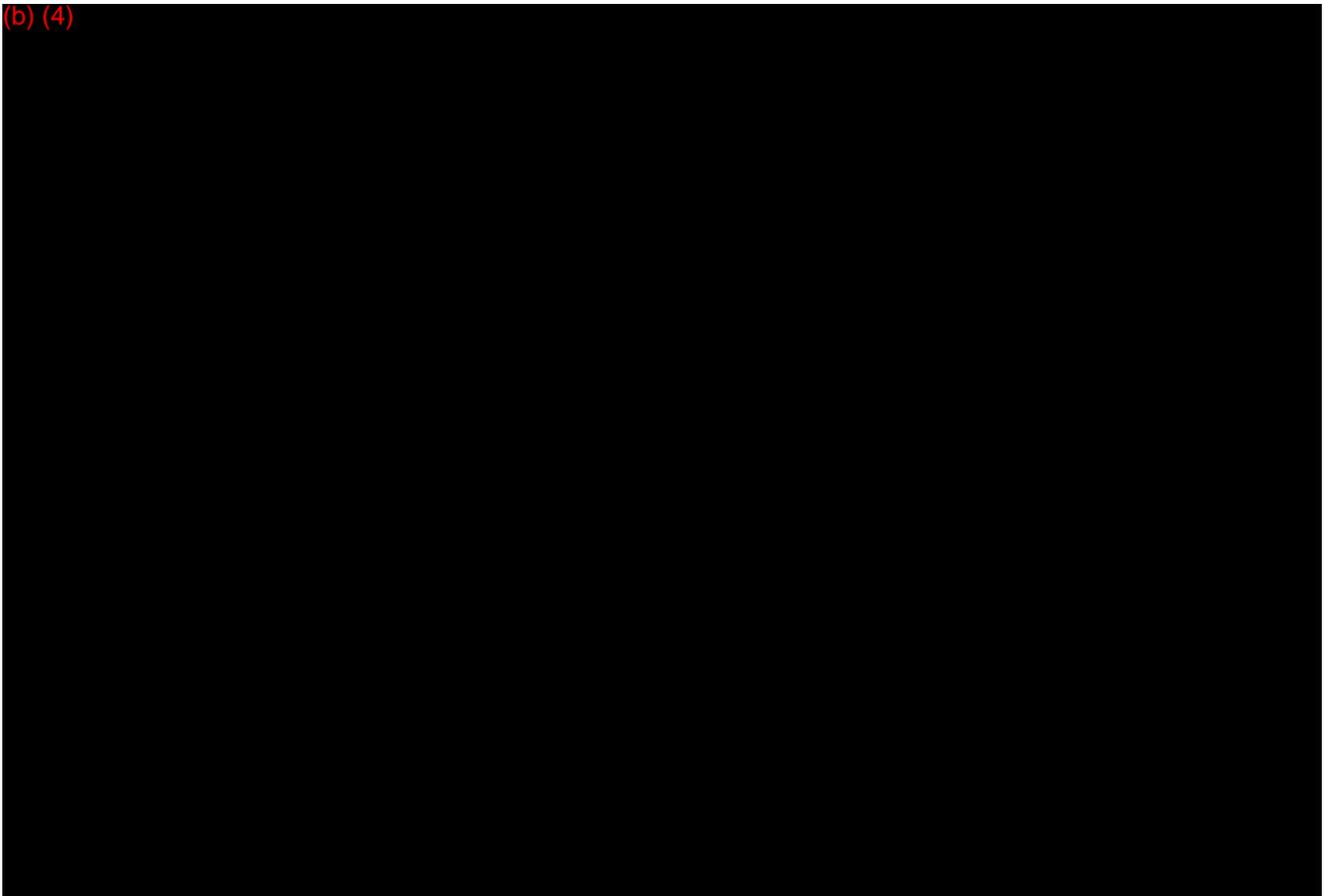
A high level summary of all changes is provided in the table below.

Component	Description of Change	Models Affected
(b) (4)		

Component	Description of Change	Models Affected
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***Software Changes***

(b) (4)

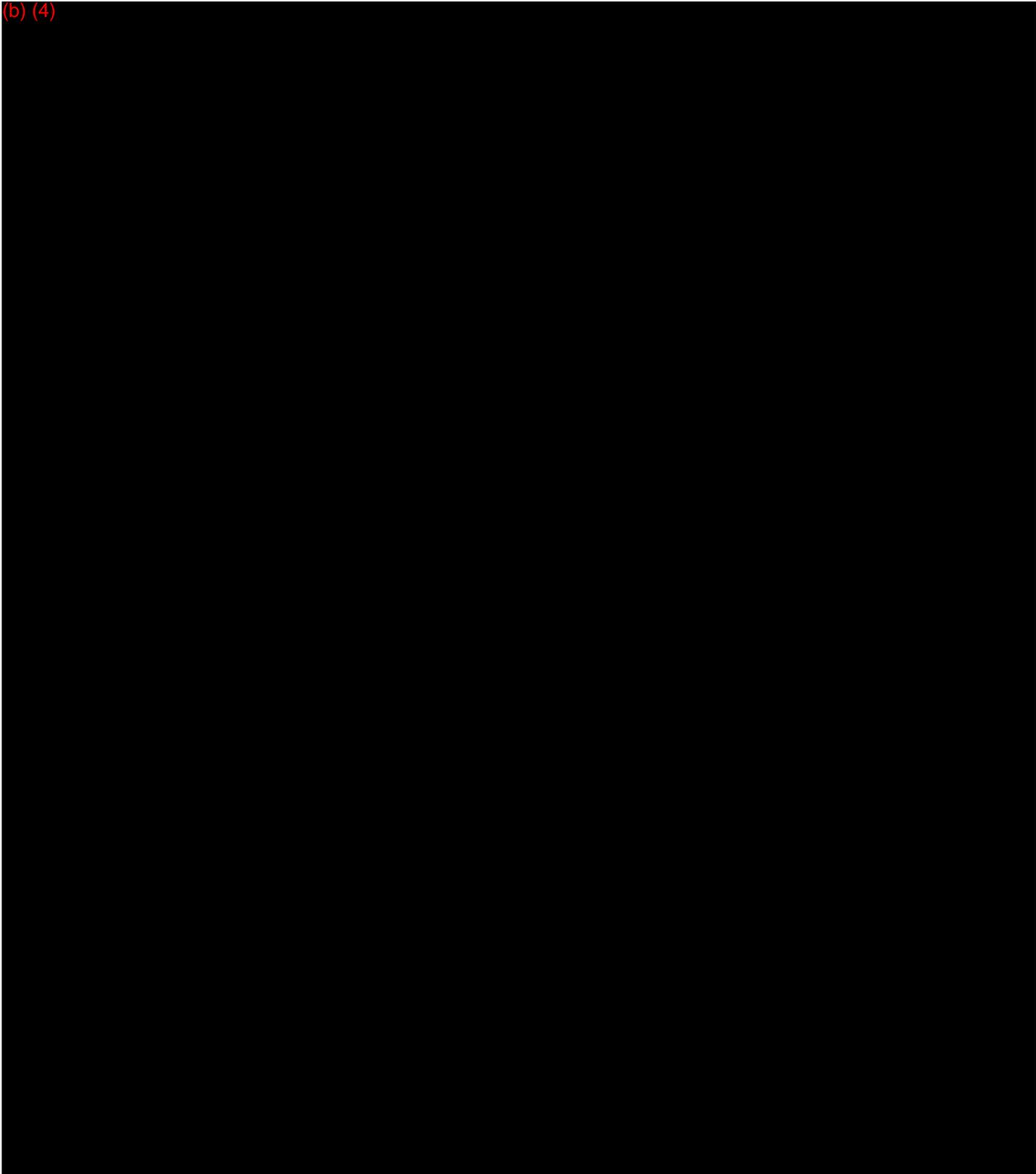


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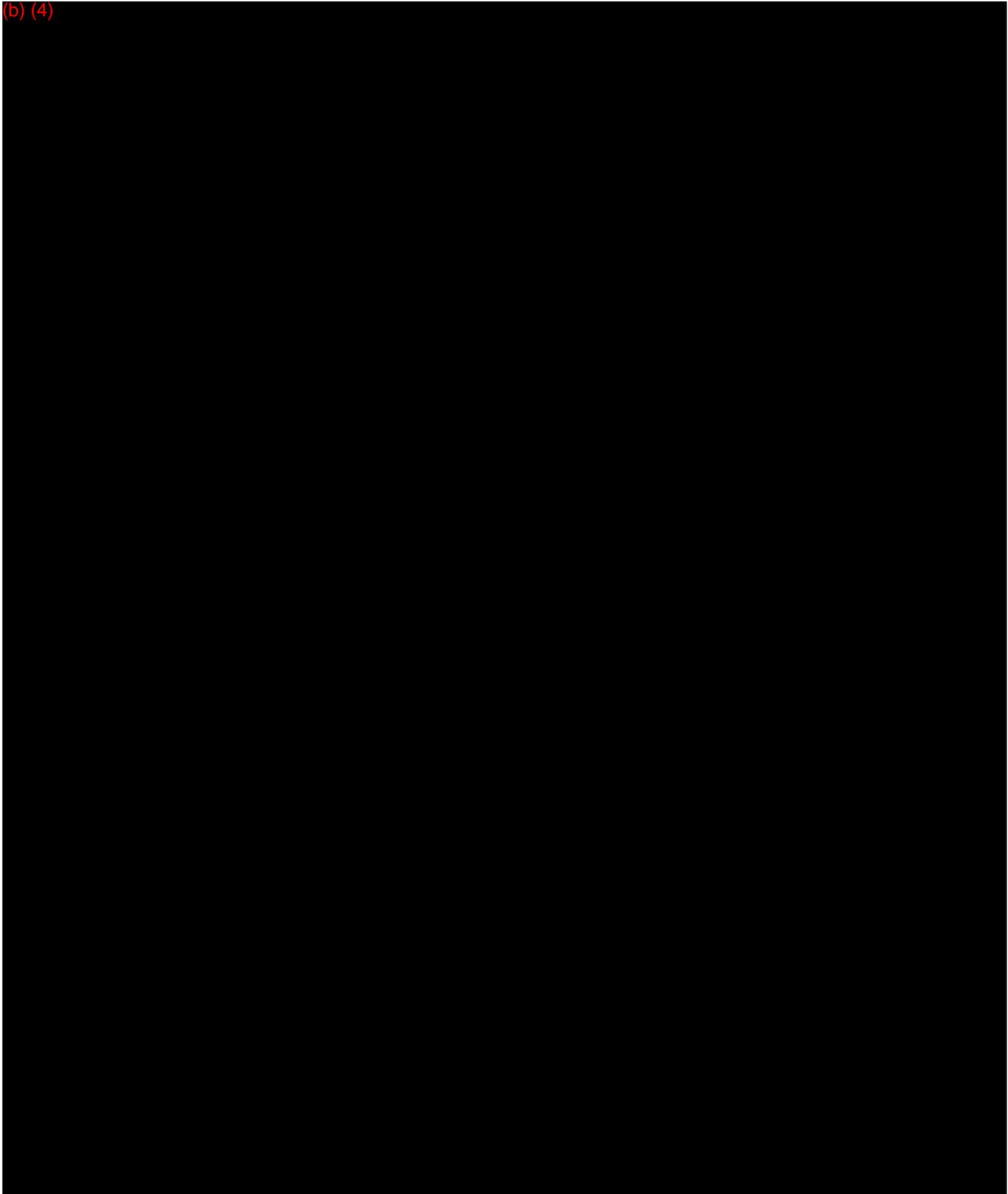
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***Hardware and Mechanical Changes***

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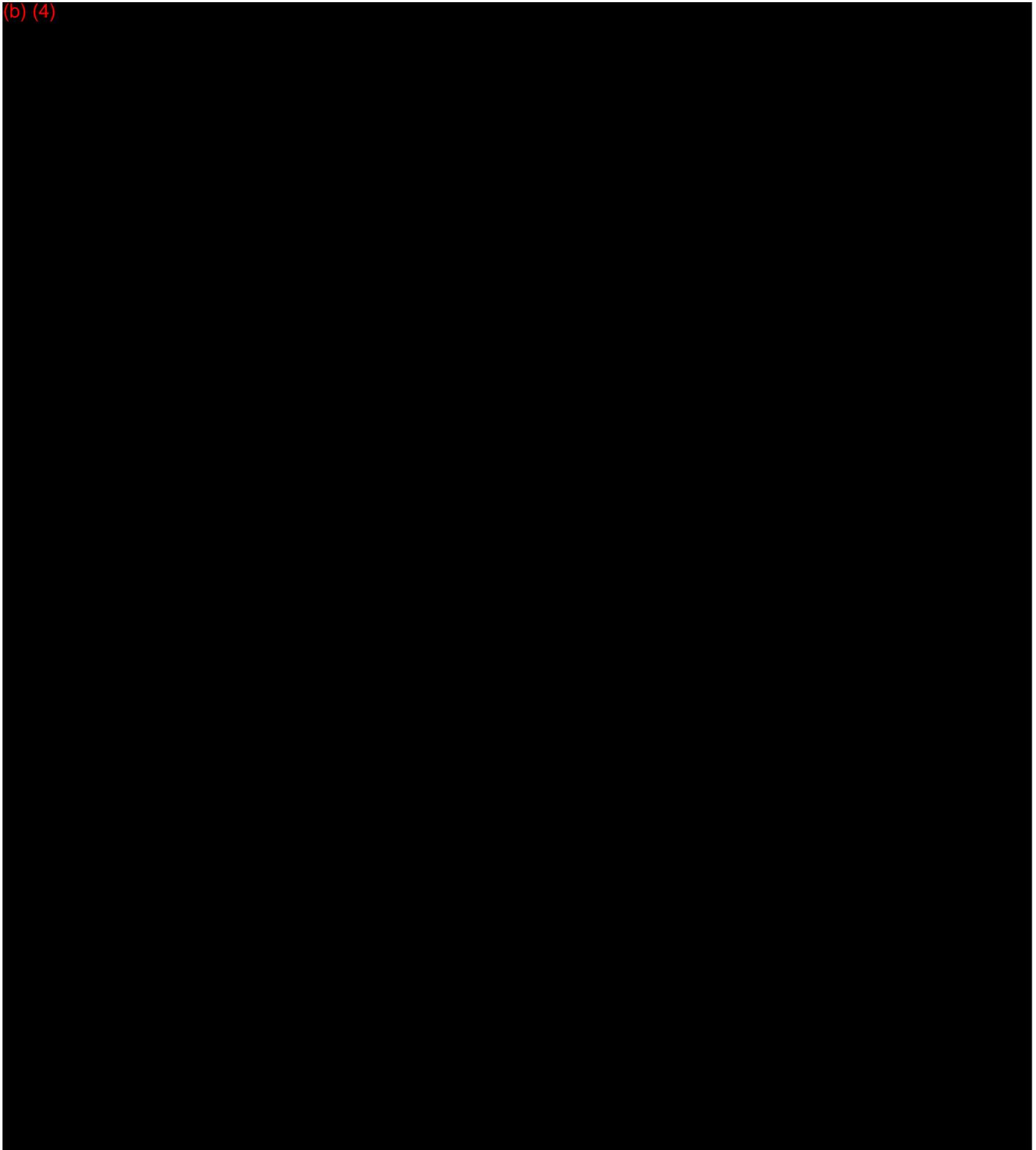


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## RISK ANALYSIS

Per the sponsor, risk analysis of these changes demonstrates the residual safety risk associated with the system is acceptable for normal product use.

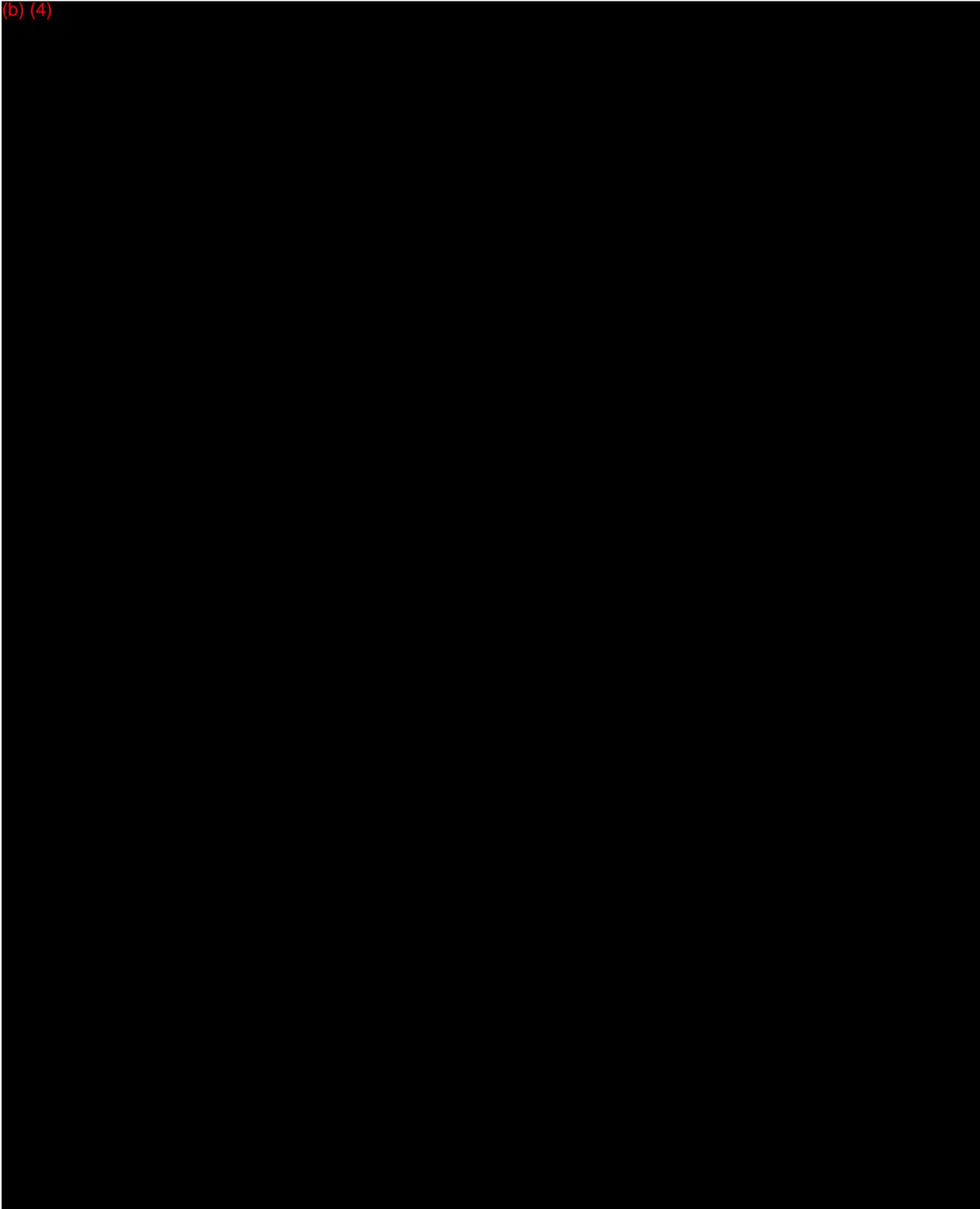
(b) (4)



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**NON-CLINICAL LABORATORY STUDIES**

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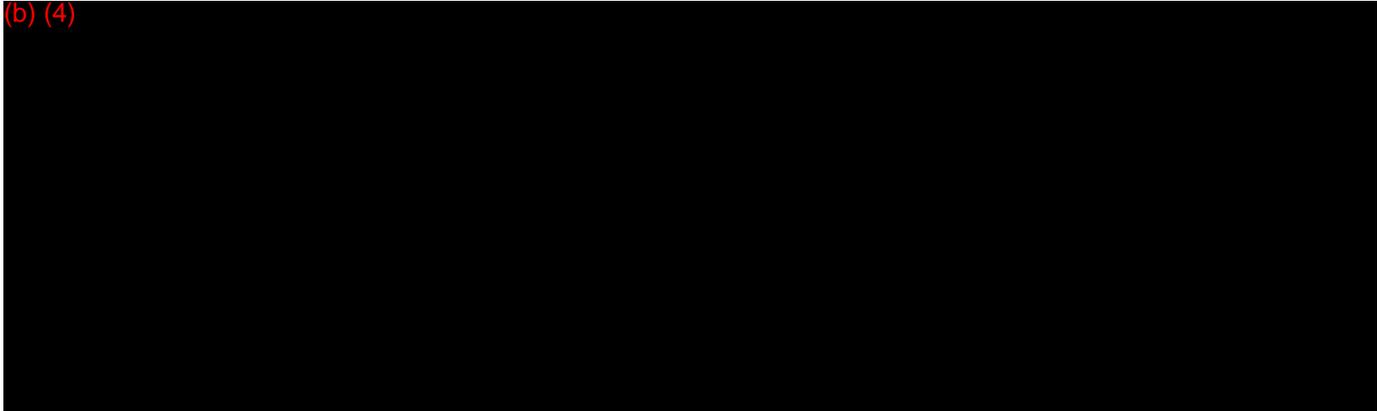


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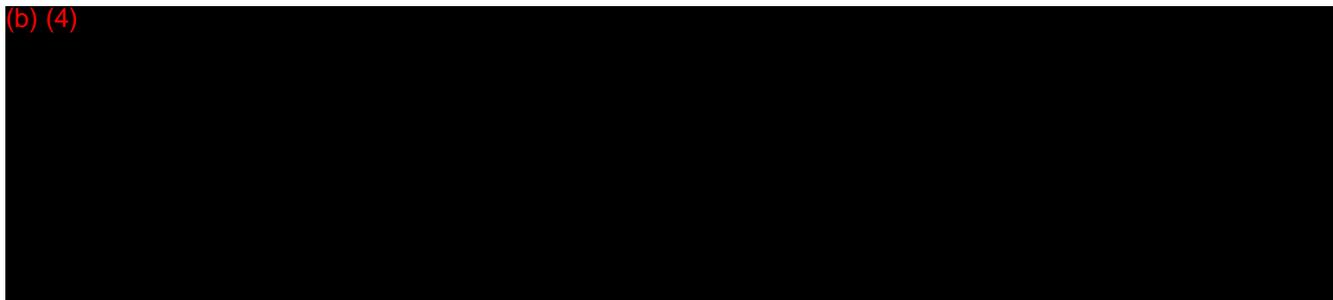
**DESIGN ANALYSIS AND EVALUATION TESTING**

(b) (4)



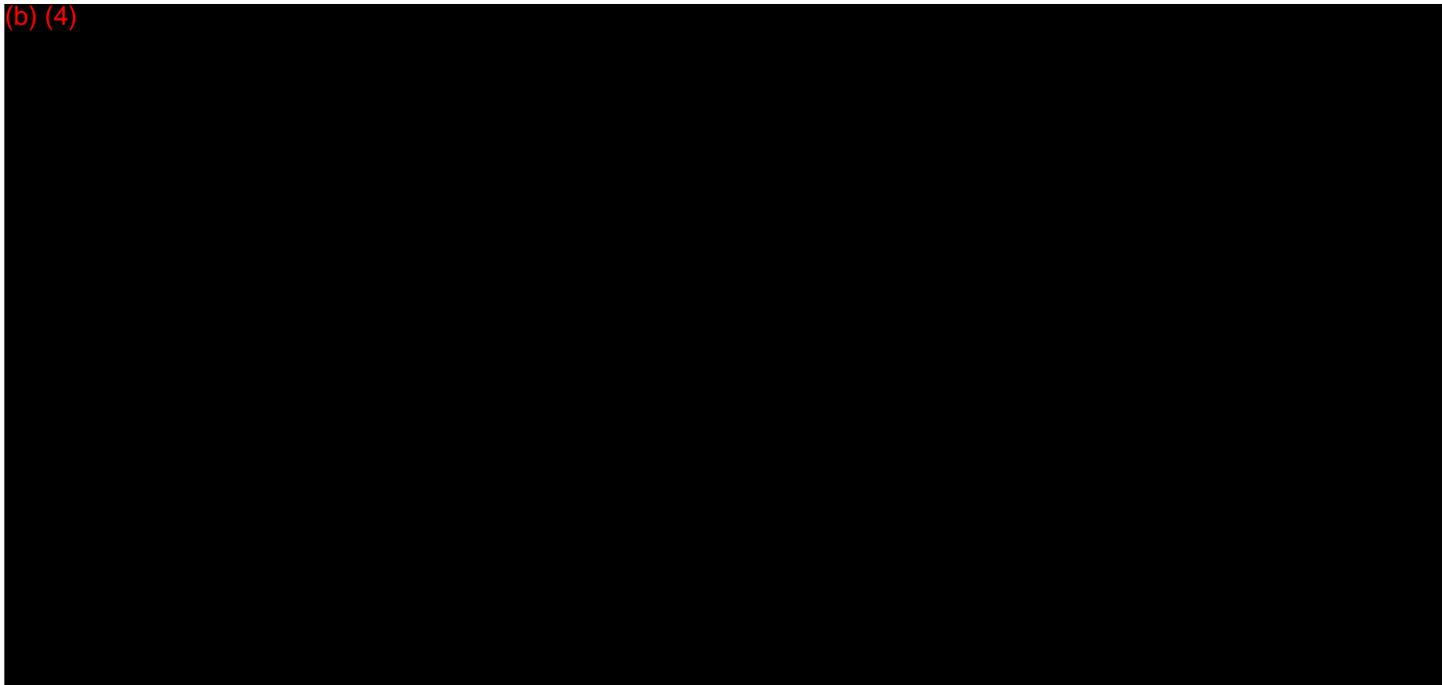
**BATTERY REVIEW**

(b) (4)



**MANUFACTURING**

(b) (4)



(b) (4)

***Design Control Information***

(b) (4)

***Major Manufacturing Changes***

There are no major manufacturing changes required to implement the changes proposed in this submission. Minor changes related to the implementation of the hardware changes are described in (b) (4) the submission.

***Design and Manufacturing Sites***

(b) (4)

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**LABELING**

***Reference Guide and Physician's Technical Manuals Modifications***

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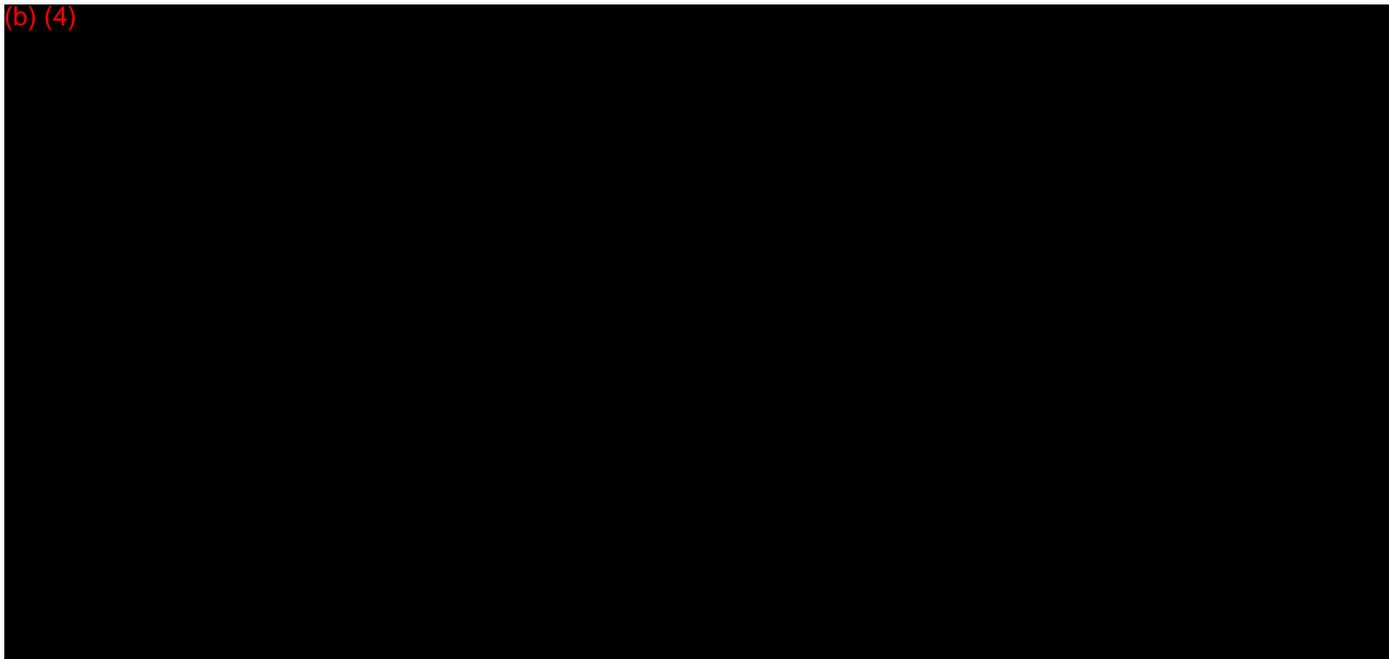
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## PROGRAMMER CAPABILITY

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## OTHER REVIEW ELEMENTS

The following areas are not relevant for the subject review:

- Animal Testing
- EMC/EMI
- Biocompatibility
- Human Factors
- Packaging, sterilization, shelf-life
- Marketing
- Post Market

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## SUMMARY OF INTERACTIONS

Oct 30, 2012 Email sent to sponsor with additional questions about the battery modification  
Nov 9, 2012 Response from sponsor to additional battery related questions  
Nov 13, 2012 Email sent to sponsor about programmer software question  
Nov 14, 2012 Response from sponsor about programmer software question

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**CONCLUSION/RECOMMENDATION**

Based on the information in the file, the sponsor has shown that the modifications identified in the submission are safe and effective at this time.

I recommend that the sponsor receive an **APPROVAL** letter.