



---

**MEMORANDUM**

**SUMMARY OF:**

P880086/S202  
Identity, Integrity, Microny, Victory, Zephyr, and Accent Pacemaker Models  
P910023/S263  
Epic, Atlas, Current and Fortify ICD Models  
P030035/S082  
Frontier II Pacemaker Models  
Anthem CRT-P Models  
P030054/S188  
Promote and Unify ICD Models  
Promote and Unify CRT-D Models

*St. Jude Medical*

---

**BACKGROUND**

This PMA supplement was submitted to gain approval for an alternative (b) (4) material for use in manufacture of the company's pacemakers, CRT-Ps, ICDs, and CRT-Ds. The current manufacturer will no longer be making their medical grade material, but will instead be providing a "biograde" version. In the subject devices, (b) (4) is used in the connector assemblies to provide strain relief, provide electrical isolation, and ensure epoxy does not enter the connector block during manufacture.

The firm conducted extensive bench and biocompatibility testing results to indicate that the new material did not impact product performance and that it was biocompatible. After the several rounds of review detailed below, this testing was deemed sufficient to support approval of the new material. Note that communication with the holder of the material master file for the (b) (4) was also necessary to address all review concerns.

Original Submission- received 19 April 2011; (b) (4)  
A001- received 29 September 2011; (b) (4)  
A002- received 16 February 2012; (b) (4)  
A003- received 02 August 2012; approval letter recommended  
A004- received 23 August 2012; contact change did not require response

---

**INDICATIONS FOR USE**

The indications for use are not affected by the change in material.

---

**DEVICE DESCRIPTION AND CHANGE DESCRIPTION**

The devices subject in this submission include pacemakers, CRT-P's, ICDs, and CRT-D's. The change itself impacts the header regions of these devices, including the strain relief, seal

assemblies, and shells used to hold components together within the connector assembly.

The firm requests approval for an alternate (b) (4) material and indicates that the change is not in response to field issues or complaints; no changes have been made to design or performance specifications. The main difference between the proposed material and the currently used material is that the new material has a (b) (4) (b) (4)

---

## RISK ANALYSIS

The firm evaluated the proposed material change for its impact on the Risk Management Report. No new risks or changes to the current risks were identified. Since there is no new information in the report and no new risks would be expected as a result of the change, this information was found acceptable.

---

## PRECLINICAL TESTING

In order to ensure that the devices with the new material still met product specifications, the firm conducted the following design verification and validation activities:

- Sterilization
- Temperature cycling
- Dimensional inspection
- Insertion/withdrawal forces
- Electrical isolation
- Dielectric strength (only for the high voltage devices)

The firm was asked several interactive questions regarding the following:

- Clarification on the function of the components in which the material is being changed
- Comparison of the material properties of the new material relative to the current
- Rationale for not conducting some additional testing
- Rationale for selection of test specimen
- Clarification on any differences between tested specimens and final product
- Details of test set-ups
- Explanation of test failures

This additional information was reviewed and found acceptable and supportive of approval; the sample sizes used were considered appropriate as were the acceptance criteria. Methods were conducted in accordance with the appropriate standards and reflect the performance needs as evaluated for the predecessor products.

---

## BIOCOMPATIBILITY

The firm provided results from biocompatibility testing on both the (b) (4) and the (b) (4) (b) (4). The firm stated that this (b) (4) is used (in its (b) (4) (b) (4)) as tissue (b) (4) for greater than 30 days. The following tests were conducted:

(b) (4)

(b) (4)

The following tests were not conducted. Rationale was provided based largely on the chemical equivalence of the new material to the currently used material and the results of chemical characterization testing.

- Chronic Toxicity
- Carcinogenicity

Several biocompatibility reviewers from ODE and OSEL participated in the review of the new material. Biocompatibility testing deficiencies were included in all rounds of review. Additional information was requested regarding the test methods and reports, and a more detailed toxicological risk assessment was needed. Once the firm provided the (b) (4) and a right to reference it, FDA directed several questions regarding biocompatibility testing to the (b) (4). All concerns have been addressed at this point in time- the appropriate testing appears to have been conducted with acceptable results.

---

#### **PACKAGING, SHELF LIFE, AND STERILIZATION**

The firm proposed no changes to the shelf life of the subject devices as a result of the material change (18 months). No changes are being proposed to sterilization processes or packaging.

A rationale for not conducting shelf life testing was requested interactively from the firm; their rationale, which pointed to the similarity between the proposed and current materials as well as the successful completion of the preclinical testing, was deemed acceptable. There were no concerns with the absence of testing on sterilization nor packaging because the proposed change would not be believed to impact either of those issues; note that biocompatibility and preclinical testing appropriately assessed final, sterilized, packaged product.

---

#### **OTHER REVIEW ELEMENTS**

The following areas are not relevant for the subject review:

- Clinical
- Animal Testing
- Software
- EMC/EMI
- Manufacturing
- Labeling
- Marketing
- Post Market

---

## SUMMARY OF INTERACTIONS

16 June 2011	Email sent to sponsor with additional questions
17 June 2011	Email sent to sponsor with additional questions
01 July 2011	Response from sponsor to additional questions
06 July 2011	Response from sponsor to additional questions
07 July 2011	Email sent to sponsor with additional questions
13 July 2011	Response from sponsor to additional questions
26 July 2011	Call to sponsor to request additional information
26 July 2011	Response from sponsor to additional information request
27 July 2011	Response from sponsor to additional information request
28 July 2011	Response from sponsor to additional information request
18 Oct 2012	Email sent to sponsor with additional questions
18 Oct 2012	Response from sponsor to additional information request
27 Nov 2012	Email sent to sponsor with additional questions
28 Nov 2012	Response from sponsor to additional information request

---

## CONCLUSION/RECOMMENDATION

Based on the information in the file and provided during interactive review, there does not appear to be an impact on safety or effectiveness when the proposed alternate polysulfone material is used in comparison to the current approved material.

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