

**SUMMARY OF: P960042/S043**

**SPECTRANETICS SLS II AND GLIDE LIGHT LASER SHEATHS**

**EXECUTIVE SUMMARY/BACKGROUND**

This PMA/S was submitted to gain approval for a material change for the (b)(4) Trade Secret inner liner used to manufacture the subject laser sheath devices. The liner is the innermost lumen of the laser sheaths (b)(4) Trade Secret

The firm provided verification bench testing, biocompatibility testing, risk management activity documents, and manufacturing work instructions and flow charts to support the proposed change. After a review of the information provided, several concerns were identified and communicated in a Major Deficiency letter date 04 Feb 2013. Responses to the concerns were provided in an amendment to the PMA/S and included additional rationale and testing. Review of this additional information addressed all initial concerns and; therefore, approval is recommended at this time.

**DESCRIPTION OF CHANGES/ REASON FOR SUPPLEMENT**

The supplier of the (b)(4) Trade Secret material used currently for the inner liner will be discontinuing the material; therefore, the firm is proposing to replace the material with another (b)(4) Trade Secret from the same supplier. The principal constituent in both materials is (b)(4) Trade Secret. No filler, reinforcements, flame retardants, heat stabilizers, or anti-oxidants are added to either the current or proposed materials. The material properties for the raw materials are provided, with the firm noting that the only notable material property differences are (b)(4) Trade Secret

**INDICATIONS FOR USE**

The firm indicates that neither the indications nor the contraindications for use have changes for the subject devices. The proposed change would not be expected to impact either the indications or contraindications for change; therefore, this section is acceptable.

**DEVICE DESCRIPTION**

The subject laser sheaths are used intra-operatively to free a chronically implanted pacing or defibrillation lead. The kits include a 12F, 14F, or 16F laser sheath, two outer (mechanical) sheaths, and a fish tape. The SLS II family of devices operates at 40 Hz maximum repetition rate, while the GlideLight family of devices operates at 80 Hz maximum repetition rate.

The laser sheaths themselves consist of (b)(4) Trade Secret

The inner lumen of the device is designed to allow a pacing

lead to pass through as the sheath slides to the lead tip in the heart.

## **PRECLINICAL/BENCH**

### **BIOCOMPATIBILITY/MATERIALS**

The firm conducted cytotoxicity, hemolysis, pyrogenicity, and EO Residuals testing to demonstrate that the proposed material change will not impact the biocompatibility of the device. The list of testing conducted did not include several other tests that would be expected based on the type and duration of patient contact that the device will have.

The Major Deficiency letter sent to the firm requested additional rationale for not conducting all expected tests or results from these tests. Clarification was also requested regarding EO Residual testing and the degree to which tested samples were representative of final product.

In A001, the firm provided results for the following which were conducted based on FDA's letter: intracutaneous reactivity, acute systemic toxicity, direct hemolysis, and bacterial reverse mutation assay. The firm also provided a detailed risk assessment including USP Physicochemical Tests for Plastics and FT-IR analysis to compare the current and proposed polymers. The additional information and testing provided in A001 addressed all initial concerns. The testing and rationale provided support the conclusion that the new material would not be expected to impact the biocompatibility of the subject device.

### **MECHANICAL SAFETY**

The firm conducted mechanical performance and coating integrity testing to verify that laser sheaths manufactured with the proposed material perform acceptably. Rationale was provided to support the omission of some joint testing- namely, the component in which the material change is proposed to be used does not contribute to mechanical integrity at several joints, so testing of those joints was deemed unnecessary. Also, the similarity in material properties was provided as evidence supporting the expected similarity in performance of sheaths manufactured with the current and proposed materials.

The Major Deficiency letter sent to the firm requested additional clarification regarding the role of the inner liner and the construction of joints in which the inner liner is involved. Additional rationale was also requested with respect to the absence of shelf life testing to evaluate mechanical performance and coating integrity over time.

In A001, the firm provided additional visuals and detailed explanations of the role of the inner liner component and construction of joints. Additional discussion was also provided regarding the chemical similarities (and, therefore, expected mechanical similarities at time zero and over time) between the current and proposed materials. The additional information provided in A001 addressed all

initial concerns. The testing and rationale provided support the conclusion that the new material would not be expected to impact the mechanical performance of the subject device at time point zero or over its shelf life.

**NOT APPLICABLE**

The following review areas were not applicable given the change requested. The subject device does not itself contain any software although the device communicates with a laser generator. The change proposed would not be expected to impact the ability to communicate with the laser generator or to impact the current evaluation of other electrical safety/EMC issues. Further, the impact of the change proposed can be sufficiently evaluated with bench testing; therefore animal and clinical data are not necessary.

**SOFTWARE**

**ELECTRICAL SAFETY/EMC**

**ANIMAL STUDIES**

**CLINICAL DATA**

**CONCLUSION**

The firm has provided sufficient evidence to support their request for approval of a material change to the inner liner of their laser sheaths. The new material is not expected to impact biocompatibility, mechanical safety or shelf life. The information provided supports a recommendation of approval for the subject PMA/S.