



MEMORANDUM

SUMMARY OF:

P980023/S049
Linux^{smart} S DX Steroid-Eluting Single-Coil ICD Leads
Biotronik

BACKGROUND

Biotronik has requested approval for a new lead model which incorporates the “floating” atrial ring electrodes of the Kainox lead (approved 19 March 2004) into the lead design of the Linux smart SD lead (approved 17 September 2010). To support this request, the firm has provided verification and fatigue bench testing as well as data regarding clinical experience with the subject lead OUS and clinical experience with the two predecessor leads.

(b)(4) Trade Secret

After reviewing the provided information in conjunction with the previously reviewed PMA/S materials and the clinical data provided interactively, the team believes the mechanical testing and clinical experience presented are supportive of approval.

INDICATIONS FOR USE

The subject lead system is intended for use in the right ventricle of patients for whom implantable cardioverter defibrillators are indicated. The lead is specifically indicated for use as a system that includes itself as well as a Lumax VR-T DX ICD.

This indications statement is acceptable for the proposed intended use and based on the supporting data. The firm has specifically called out that the lead is part of a system and cannot be used with any ICDs other than those for which it is designed to be used with. There are no concerns with this section.

DEVICE DESCRIPTION

The Linux smart S DX steroid-eluting, single coil ICD lead system is designed to sense atrial and ventricular signals as well as deliver shocks to ICD patients with a single lead. To accomplish this function, the lead contains two floating atrial ring electrodes for the atrial sensing capabilities. These floating ring electrodes require an additional IS-1 connector be added to the lead which is accommodated by replacing the DF-1 connector of the SVC coil. The lead is said to be

“functionally equivalent” to the Kainox A+ single pass lead approved under P000009/S008 in March 2004 with the lead design based on the newer Linx smart SD lead approved under P980023/S038 in September 2010.

The lead may be used with two specific ICDs- the Lumax 540 DX and the Lumax 740 DX only.

RISK ANALYSIS

The firm updated the Risk Analysis for the Linx smart ICD family for the withdrawn PMA/S. No changes were updated for the subject PMA/S. The risks identified appear appropriate and inclusive for the intended use and design of the subject lead. There are no concerns with this section.

PRECLINICAL TESTING

The firm conducted a suite of design verification and fatigue testing to demonstrate acceptable performance of the proposed lead. Several deficiencies were sent initially under P980023/S045 regarding fatigue testing methods, sample sizes, acceptance criteria, and preconditioning. Deficiencies were also sent regarding the sample sizes used in verification testing, helix functionality evaluation, testing of the new connector, and electrical sensing characteristics of the lead in comparison to the Kainox A+ single pass lead. The firm responded to the Major Deficiency letter with additional testing and rationales, which were deemed acceptable and to have addressed all issues. The data presented is supportive of good chronic performance of this new lead, and no concerns remain with this section.

CLINICAL EXPERIENCE

Under P980023/S045, the firm provided no clinical data for the proposed lead, but did reference US and OUS data on leads similar to the predecessor lead (the Kainox VDD/Deikos A+ lead). A deficiency was sent noting that data from the Kainox lead could not be leveraged to support approval of the subject lead based on the degree of differences between the two in design and construction. The firm was requested to provide data for the predecessors themselves (Kainox A+ and Linx smart SD) as well as to provide more details on the OUS experience available thus far for the proposed lead, which has received CE mark. A separate deficiency was sent requesting details on how the atrial sensing electrode surface area changes might impact the clinical performance of the new lead in comparison to the Kainox A+ lead.

In the subject PMA/S, the firm provided clinical data on the predecessor Linx SD leads from the GALAXY and CELESTIAL post approval studies, each of which are planned for 5 years. Note that the GALAXY trial is a voluntary study. The firm also provided information on complaints received thus far for the Linx S DX subject lead after CE mark and complaint records for the predecessor VDD leads (Kainox). The firm provided data on the 61 total subjects enrolled in two separate European studies for the subject lead. Information was also provided on the very limited studies conducted initially on the predecessor VDD leads.

Initially, the review team believed a Post Approval Study (PAS) would be necessary to confirm the good, but limited, performance provided in the submission and to better characterize the chronic performance of the subject lead. Through interactive discussions, the firm provided new clinical data that described the clinical experience with the subject lead as collected in a prospective, OUS study. This data, in combination with the data and information presented in the submission, is supportive of good performance of the subject lead. Given the following, no additional clinical data (pre or post market) is needed to support approval:

- There is no concerning safety signal with the clinical experience provided in this submission for the predecessor leads or the subject lead. The experience provided, when looked at collectively and in totality, is sufficient with respect to duration and scope given the scope of the changes proposed.
- There is a high degree of similarity between the subject lead and the Linx predecessor lead regarding design and potential failure modes such that the experience of the predecessor lead is believed to be sufficiently representative of that of the subject lead.

BIOCOMPATIBILITY

Under P980023/S045, the firm indicated that all materials are identical to market-approved Linx predecessor lead. The sponsor confirmed that there are no changes to the materials of the proposed lead under the subject submission in comparison to the withdrawn PMA/S. As is documented during the review of the withdrawn PMA/S- the firm's rationale for not conducting biocompatibility testing is acceptable given that there are no new materials or manufacturing processes for the proposed device.

PACKAGING AND STERILIZATION

Under P980023/S045, the firm indicated that no changes had been made to either sterilization or packaging. The firm provided details of each within that submission. The sponsor confirmed that there are no changes to the sterilization process or packaging of the proposed lead under the subject submission in comparison to the withdrawn PMA/S. As is documented during the review of the withdrawn PMA/S- there are no concerns with the sterilization or packaging given that they are well described and identical to a market-approved predecessor.

SHELF LIFE

The firm has requested a shelf life of two years for the proposed lead. Limited verification testing on aged product was provided under P980023/S045. In response to the Major Deficiency letter, clarification was provided regarding the results that testing. With this response, all concerns have been addressed and that the aging data presented is supportive of good performance of this new lead throughout its shelf life. No concerns remain with this section.

MANUFACTURING

The firm indicated the facilities at which the subject lead will be manufactured. These facilities are the same facilities employed in the manufacture of all leads and accessories currently distributed by BIOTRONIK, Inc. in the United States, including the market released Linxsmart SD and Linxsmart TD leads (P980023/S038, approved on September 17, 2010). There are no concerns with this section.

LABELING

Under P980023/S045, the firm provided new labeling for the proposed lead. Several deficiencies were sent regarding the content of this labeling including the need to clarify that the lead has only one shocking coil, the potentially exculpatory nature of the trade name proposed, and the need for language that educates the user on selecting an appropriate length (including distance between atrial sensing electrodes) for the patient.

Within the subject PMA/S, the firm clarified within the packaging labeling and technical manual

that the lead has only one shock coil; this firm also withdrew the request for the proposed trade name.” Following interactive email communication, the firm updated their labeling to include language to educate the user on selecting an appropriate length lead. The firm also updated their labeling with information from the two European clinical trials for the subject lead and a clarification statement that no mandatory reporting clinical data has been collected on atrial sensing complications rates.

The labeling presented under the subject file was deemed acceptable with the modifications agreed to interactively- the labeling adequately informs the user of the device, how it should be used, and its expected performance.

OTHER REVIEW ELEMENTS

The following areas are not relevant for the subject review:

- Animal Study
- Software
- EMC/EMI

CONCLUSION/RECOMMENDATION

Based on the information in the file and provided during interactive review, there are no outstanding concerns with the safety or effectiveness of the subject lead. I recommend that the sponsor receive an **APPROVAL** letter.