
**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**



*Division of Cardiovascular Devices
Pacing, Defibrillator & Leads Branch*

Date: 16 Feb 2012

From: [REDACTED] Biomedical Engineer, FDA/CDRH/ODE/DCD/PDLB

Subject: P980023/S046
Biotronik
Vigila and Volta ICD leads

Recommendation: **APPROVAL**

[REDACTED]	Lead Reviewer, PDLB	Date	Mitchell Shein, Chief, PDLB	Date
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EXECUTIVE SUMMARY

This PMA supplement was submitted to gain approval for modifications to the indications for use statements for the firm's Linx and Linx smart ICD leads. With these changes, the existing products will be marketed under the Vigila and Volta trade names by Sorin. The firm also proposes to distribute separate lead accessory kits for use with Sorin-distributed leads and to modify the existing lead packaging to match the appearance of Sorin CRM's distributed leads.

The firm provides the following information in support of their proposed changes:

- Retrospective analysis of clinical data for patients implanted with Linx (Biotronik) leads in conjunction with Sorin ICDs
- Review of complaint database for issues regarding lead incompatibility with other manufacturers' devices
- Validation testing of compatibility of leads with the relevant components of the accessory kits and with other manufactures' ICDs

Based on my review of this submission and the feedback received from other reviewers, I believe this submission should be Approved. The main potential concern with the proposed change is incompatibility of Biotronik leads with other manufacturers' pulse generators. The firm has provided both bench and clinical evidence to reasonably support that this compatibility is not an issue.

Review Team

Clinical-[REDACTED] MD, FDA/CDRH/ODE/DCD/PDLB
Engineering-[REDACTED] FDA/CDRH/ODE/DCD/PDLB

Distribution Agreement

A detailed description of the Registration and Reporting Agreement between Biotronik and Sorin is provided in section 3.1. Biotronik manufactures the devices and is also responsible for MDR reporting and communicating any recall issues to FDA. Sorin maintains implantation records and is responsible

for providing Biotronik with failures it notices and (as necessary) assisting in any FDA communications.

Indications For Use

The current indications statement includes the specification that the leads are only to be used “in conjunction with a Biotronik ICD.”:

Current Indication for Use:

The Linx smart/ Linx Lead System is indicated for use in conjunction with a BIOTRONIK ICD. Currently, data is not available regarding the use of this lead system with ICDs of other manufacturers. Use of other ICDs may adversely affect sensing and/or therapy delivery.

The proposed change is to remove the distinction that the lead can only be used with Biotronik devices:

Proposed Indication for Use:

The VIGILA/VOLTA/Linx/ Linx smart 8F steroid-eluting, bipolar, IS-1 transvenous lead system is intended for use in the right ventricle of patients for whom implantable cardioverter defibrillators are indicated.

Device Description

A detailed device description is provided on pages 9 and 10 of the submission. More generally, the subject Vigila/Volta/Linx/Linx smart ICD leads are 8F, steroid-eluting, bipolar, transvenous leads with IS-1 and DF-1 connectors. Both the Vigila and Volta leads are available in active and passive fixation models with either one or two high voltage coils. The difference between the Vigila and the Volta devices is the same as that between the Linx and Linx smart leads: the Volta and Linx smart leads have a (b) (4), while the Vigila and Linx leads do not.

Detailed Description of Changes

Change #1: Indications Statement (see the Indications for Use section above)

LEAD REVIEWER COMMENTS: The changes to the indications for use statement were reviewed by both engineering and clinical reviewers. Their comments are provided in response to the relevant testing and clinical study sections below.

Change #2: Distribution of Accessory Kits with the New Sorin CRM leads (Vigila and Volta)
With the exception of the differences below, the accessory kits are identical to those supplied with the corresponding Biotronik leads.

- The lead fixation sleeve supplied with the Vigila and Volta leads is different than that provided with the Linx leads. The Sorin fixation sleeve is a previously approved version that includes a spiral slit along the longitudinal side to allow for mounting. This same sleeve is available for use with the Linx leads, but not sold in a specific accessory kit.
- The accessory kits for passive and active fixation leads are the same and will include only the S xx-K and S xx-C stylets. Only one accessory kit is offered for use with all of the Vigila and Volta models. To ensure that accessories were not used with incompatible leads, those accessories specific to only one lead model were not included in the kit. More specifically, the model-specific stylet S xx-A which should not be used with active fixation models is not included in the accessory kit.
- The accessory kit will only include the unipolar stylet guide (not the bipolar stylet guide as well). As with the stylets, only one accessory kit is offered for all lead models, so only the unipolar guide is provided since it is the only model compatible with all Vigila and Volta models.

- Color of the packaging box is now orange vs blue.

LEAD REVIEWER COMMENTS: The changes to the accessory kit were reviewed by myself as the engineering consultant in a memo dated 16 Feb 2012. Clarifications were requested of the sponsor interactively (via email 10 Feb 2012 and telephone 13 Feb 2012) regarding the rationale for not providing all accessories with all products and the use of the subject suture sleeve with the approved Linux leads. All questions were addressed (as indicated in the engineering memo) and no concerns remain with this section.

Change #3: Updates to Labeling to Conform with Sorin styling/formatting

- Size of outer and inner box labels has changed, but contents have not
- Color and markings on box have changed to reflect Sorin's packaging standards
- Printed manual will be provided for Sorin leads whereas manuals are only available online for Biotronik leads
- References within manual to Biotronik has been switched to Sorin as appropriate
- Sorin's lead registration form is now provided

LEAD REVIEWER COMMENTS: The above changes appear acceptable and appropriate. The contents of the labeling and manuals are the same and these changes to formatting are not concerning.

Preclinical/Bench Evidence

The firm conducted testing to confirm that all documentation was included in the final package appropriately (Appendix 14), that the suture sleeve included in the accessory kit was compatible with the Vigila and Volta leads (Appendix 15), and that the components met the Bill of Materials (Appendix 16). The firm also provided electrical compatibility testing to determine if the Biotronik leads were more susceptible to oversensing than the Sorin leads when used with a Sorin ICD (Appendix 13).

LEAD REVIEWER COMMENTS: The provided bench testing is reviewed in detail in the engineering review memo, which indicates that the testing was well documented and demonstrative of acceptable controls for documentation and compatibility of the already-approved suture sleeve with the already-approved lead design. Further, the general engineering concerns of terminal compatibility and the ability of the Biotronik lead to be used with other manufacturers' ICDs to sense and delivery appropriate therapy were discussed. The reviewer concluded that the provided testing in addition to a general engineering understanding of the devices is supportive of approval from an engineering perspective.

Packaging, Shelf Life, and Sterilization

The firm indicates that the packaging and sterilization method for the Sorin CRM leads and the Accessory Kit is identical to that approved for the corresponding Biotronik leads (P950037/S044). The shelf life is proposed to be 24 months, also identical to that of the Linux approved leads.

LEAD REVIEWER COMMENTS: The changes proposed would not impact the acceptability of the currently approved shelf life, packaging or sterilization method; therefore, there are no concerns with this section.

Biocompatibility

The firm indicates that there are no changes to the materials used in the subject lead or accessories.

LEAD REVIEWER COMMENTS: The changes proposed would not impact the biocompatibility of the device (or the acceptability of FDA's previous decision); therefore, there are no concerns with this section.

Clinical Data

The firm conducted a retrospective analysis of past clinical studies in which Biotronik leads were paired with devices from other manufacturers: 93 patients implanted with Sorin ICDs and Biotronik Linx leads and 138 patients implanted with Sorin devices and other ICD leads. A review of both Biotronik and Sorin's device tracking databases was conducted to identify instances where Biotronik leads were used with other manufacturers' devices or (for Sorin's database) when Biotronik leads were used specifically with Sorin products. No complaints were issued regarding compatibility of the leads and devices for those cases.

LEAD REVIEWER COMMENTS: [REDACTED] reviewed the firm's clinical evidence and indicated he has no concerns with the proposed indication statement change based on the following: The submitted retrospective clinical data analyses are helpful and supportive of the conclusion that mixing devices and leads between manufacturers does not cause compatibility issues for performance.

Risk Management

The firm conducted a risk analysis for the proposed changes (Appendices 1 and 2).

LEAD REVIEWER COMMENTS: These documents were reviewed and found appropriate for the devices subject here.