

Section 3 **Summary of Safety and Effectiveness**

The Novacor® Left Ventricular Assist System (LVAS) is an approved device (PMA P980012, September 29, 1998). FDA provided the Summary of Safety and Effectiveness to the sponsor on August 3, 1999 [photocopy provided in Attachment 3.A].

Proposed changes to the Summary of Safety and Effectiveness (i.e., labeling) are discussed in Section 4 of the Panel Pack. An update to the Summary of Safety and Effectiveness will be derived from the final labeling following FDA approval. The revised sections of the Summary of Safety and Effectiveness will include, but may not be limited to:

- General Information
- Indications and Usage
- Device Description
- Summary of Pre-Clinical Studies - Reliability
- Panel Recommendation

The following table provides a draft of proposed changes to the Summary of Safety and Effectiveness.

**Proposed Changes to the
Current Summary of Safety and Effectiveness Data (SSED)**

Section	Description	Current SSED	Proposed SSED
1	General Information	Baxter Healthcare Corporation Novacor Division	World Heart Inc.
2	Indications and Usage	The LVAS is intended for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from nonreversible left ventricular failure. The LVAS is indicated for use both inside and outside of the hospital.	The LVAS is intended for use as a short or long-term bridge to transplantation in cardiac transplant candidates, and in patients with relative contraindication to transplantation who are expected to become transplant candidates with mechanical circulatory support, at risk of imminent death from nonreversible left ventricular failure. The LVAS is indicated for use both inside and outside of the hospital.
5	Device Description	Compact Controller	Controller
9	Summary of Pre-Clinical Studies	See Attachment 3.A	See Attachment 4.B. Changes described in . currently under FDA review
12	Panel Recommendation	See Attachment 3.A	Change to reflect outcome of June 8, 2004 Circulatory System Devices Panel review