

## **Table of Contents**

- 1. FDA Executive Summary**
- 2. FDA Questions**
- 3. PMA Voting Options**
- 4. Sponsor Executive Summary**
- 5. Proposed SSED (Summary of Safety and Effectiveness Data)**
- 6. Proposed Package Insert**
  - a. Optimizer SMART IPG Instructions for Use (IFU)**
  - b. OMNI II Programmer System and Optimizer Mini Charger Instructions for Use (IFU)**
- 7. Proposed Patient Labeling**
  - a. Optimizer SMART System Patient's Manual**
- 8. Proposed Post-Approval Study**
- 9. Appendices**
  - a. FIX-HF-5C Study Paper 2018**