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