

TABLE OF CONTENTS

| TITLE | TAB |
|--|------------|
| FDA Executive Summary | 1 |
| FDA Questions | 2 |
| PMA Voting Options | 3 |
| CDs for Panel | 4 |
| Sponsor Executive Summary | 5 |
| Proposed SSED (Summary of Safety and Effectiveness Data) | 6 |
| Proposed Package Insert | 7 |
| Proposed Patient Labeling | 8 |
| Proposed Post-Approval Study | 9 |
| Appendix 1 - Use of Real-World Data from European Patient Registry | 10 |
| Appendix 2 - Benefit Risk Assessment of Repeat Use of the CGM System | 11 |