DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

SUPPLEMENTAL DATA SHEET

FORM APPROVED: OMB NO. 0910-0138
EXPIRATION DATE: September 30, 2018
(See PRA Statement on Page 2)

Panel Recommendation

1. GENERIC TYPE OF DEVICE

2. ADVISORY PANEL

3. IS DEVICE AN IMPLANT (21 CFR 860.3)?
☐ Yes ☐ No

4. INDICATIONS FOR USE IN THE DEVICE'S LABELING

5. IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE

General

6. RECOMMENDED ADVISORY PANEL CLASSIFICATION AND PRIORITY

Classification Priority (Class II or III Only)

7. IF DEVICE IS AN IMPLANT, OR IS LIFE-SUSTAINING OR LIFE-SUPPORTING AND HAS BEEN CLASSIFIED IN A CATEGORY OTHER THAN CLASS III, EXPLAIN FULLY, THE REASONS FOR THE LOWER CLASSIFICATION WITH SUPPORTING DOCUMENTATION AND DATA

8. SUMMARY OF INFORMATION, INCLUDING CLINICAL EXPERIENCE OR JUDGMENT, UPON WHICH CLASSIFICATION RECOMMENDATION IS BASED

9. IDENTIFICATION OF ANY NEEDED RESTRICTIONS ON THE USE OF THE DEVICE *(e.g., special labeling, banning, or prescription use)*

10. IF DEVICE IS RECOMMENDED FOR CLASS I, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM

Justification/Comments

☐ a. Registration/Device Listing .....

☐ b. Premarket Notification .....

☐ c. Records and Reports .....

☐ d. Good Manufacturing Practice .....

11. IF DEVICE IS RECOMMENDED FOR CLASS II, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM PREMARKET NOTIFICATION

☐ a. Exempt

☐ b. Not Exempt

Justifications/Comments .....

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12. EXISTING STANDARDS APPLICABLE TO THE DEVICE, DEVICE SUBASSEMBLIES *(Components)* OR DEVICE MATERIALS *(Parts and Accessories)*

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13. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO:

Food and Drug Administration
Center for Devices and Radiological Health
Office of the Center Director
Regulations Staff, WO66-4436
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

This section applies only to requirements of the Paperwork Reduction Act of 1995.
Please see item 13 for the address to which you may send your completed form.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 500 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

INSTRUCTIONS FOR SUPPLEMENTAL DATA SHEET

1. The Supplemental Data Sheet should be prepared in conjunction with the General Device Questionnaire. The preparer should refer to Title 21 Part 860 of the Code of Federal Regulations for classification/reclassification definitions and procedures.

2. The Supplemental Data Sheet is designed to provide the device description, intended use, the risks of the device, the recommended class and the scientific support for the class and proposed level of controls.

3. The information requested by questions 1 through 8 must be provided for all devices.

4. Question 9 can be answered by referring to question 11 of the General Device Questionnaire.

5. Question 10 refers only to devices recommended for class I, and is a recommendation for exemptions from the General Controls listed.

6. Question 11 refers only to devices recommended for Class II.

7. Question 12 requests the listing of any existing standards for the device being classified. The standards to be listed could be standards drafted by professional groups, standards groups or manufacturers.

8. Send this completed form and the appropriate questionnaire to the address indicated in item 13.