DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

SUPPLEMENTAL DATA SHEET

FORM APPROVED: OMB NO. 0910-0138 EXPIRATION DATE: May 30, 2012 (See PRA Statement on Page 2)

Panel Recommendation		
1. GENERIC TYPE OF DEVICE		
2. ADVISORY PANEL	3. IS DEVICE AN IM	PLANT (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)		
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7. IF DEVICE IS AN IMPLANT, OR IS LIFE-SUSTAINING OR LIFE-SUPPORTING AND HAS BEEN CLASSIFIED IN A FULLY, THE REASONS FOR THE LOWER CLASSIFICATION WITH SUPPORTING DOCUMENTATION AND DATA	CATEGORY OTHER	THAN CLASS III, EXPLAIN
8. SUMMARY OF INFORMATION, INCLUDING CLINICAL EXPERIENCE OR JUDGMENT, UPON WHICH CLASSIF	ICATION RECOMMEN	DATION IS BASED
9. IDENTIFICATION OF ANY NEEDED RESTRICTIONS ON THE USE OF THE DEVICE (e.g., special labeling, bann	ing, or prescription use)
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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
12. EXISTING STANDARDS APPLICABLE TO THE DEVICE, DEVICE SUBASSEMBLIES (Components) OR DEVICE MATERIALS (Parts and Accessories)
13. COMPLETE THIS FORM PURSUANT TO 21 CER PART 860 AND SUBMIT TO: Food and Drug Administration Center for Devices and Radiological Health Office of the Center Director 1000
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 instructions for the address to which you may send your completed form.

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

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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff 1350 Piccard Drive, Room 400 Rockville, MD 20850

"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 number."

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INSTRUCTIONS FOR SUPPLEMENTAL DATA SHEET

- 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.

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