DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE --- FOOD AND DRUG ADMINISTRATION

GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE

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

PANEL MEMBER / PETITIONER	DATE

GENERIC TYPE OF DEVICE	CLASSIFICATION RECOMMENDATION

1. IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING ?	☐ YES ☐ NO	Go to Item 2.
2. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE IN PREVENTING IMPAIRMENT OF HUMAN HEALTH ?	☐ YES ☐ NO	Go to Item 3.
3. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY ?	☐ YES ☐ NO	Go to Item 4.
4. DID YOU ANSWER "YES" TO ANY OF THE ABOVE 3 QUESTIONS ?	☐ YES ☐ NO	If "Yes," go to Item 6. If "No," go to Item 5.
5. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES ☐ NO	If "Yes," Classify in Class I. If "No," go to Item 6.
6. IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* IN ADDITION TO *GENERAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES ☐ NO	If "Yes," Classify in Class II and go to Item 7. If "No," Classify in Class III.
7. IF THERE IS SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS IDENTIFY BELOW THE SPECIAL CONTROL(S) NEEDED TO PROVIDE SUCH REASONABLE ASSURANCE. FOR CLASS II. ☐ Guidance Document ☐ Performance Standard(s) ☐ Device Tracking ☐ Testing Guidelines ☐ Other *(Specify)* _____		
8. IF A REGULATORY PERFORMANCE STANDARD IS NEEDED TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF A CLASS II OR III DEVICE, IDENTIFY THE PRIORITY FOR ESTABLISHING SUCH A STANDARD. ☐ Low Priority _____ ☐ Medium Priority _____ ☐ High Priority _____ ☐ Not Applicable _____		
9. FOR A DEVICE RECOMMENDED FOR RECLASSIFICATION INTO CLASS II, SHOULD THE RECOMMENDED REGULATORY PERFORMANCE STANDARD BE IN PLACE BEFORE THE RECLASSIFICATION TAKES EFFECT ?	☐ YES ☐ NO ☐ NOT Applicable	
10. FOR A DEVICE RECOMMENDED FOR CLASSIFICATION / RECLASSIFICATION INTO CLASS III, IDENTIFY THE PRIORITY FOR REQUIRING PREMARKET APPROVAL APPLICATION (PMA) SUBMISSIONS. ☐ Low Priority _____ ☐ Medium Priority _____ ☐ High Priority _____ ☐ Not Applicable _____		

PSC Publishing Services (301) 443-6740 EF

11. IDENTIFY THE NEEDED RESTRICTION(S)

- ☐ Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device
- ☐ Use only by persons with specific training or experience in its use
- ☐ Use only in certain facilities
- ☐ Other *(Specify)*

12. 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 instructions 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 hours for this collection of information are estimated to be 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
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."

INSTRUCTIONS FOR GENERAL DEVICE QUESTIONNAIRE

1. Answer each question by checking yes or no in the middle column and follow the instructions in the column on the right. The preparer should refer to Title 21 Part 860 of the Code of Federal Regulations for classification/reclassification definitions and procedures.
2. The General Device questionnaire is designed to aid in the determination of the proper class for all medical devices.
3. A medical device should be placed in the lowest class which will provide adequate controls to reasonably assure the safety and effectiveness of the device.
4. Questions 1, 2, and 3 pertain to the degree of risk of the device and can be answered broadly.
5. Questions 8 & 9 are not applicable unless a regulatory standard, subject to section 514 of the Food, Drug, and Cosmetic Act, as amended, 1976, has been designated as a "special control."
6. Question 10 is applicable only to devices recommended for class III.
7. Question 11 refers to restriction such as prescription use or similar limitations as to the use of the device.
8. Use this completed questionnaire to prepare the Supplemental Data Sheet. Send both forms to the address indicated in question 12.