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: June 30, 2018
(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
2. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE IN PREVENTING IMPAIRMENT OF HUMAN HEALTH ?	☐ YES ☐ NO
3. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY ?	☐ YES ☐ NO
4. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES ☐ NO
5. IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* IN ADDITION TO *GENERAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES ☐ NO
6. 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. ☐ Guideline Document ☐ Performance Standard(s) ☐ Device Tracking ☐ Testing Guidelines ☐ Other *(Specify)* _____	
7. 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 _____	
8. 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
9. 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 _____	

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10. 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)* _____

11. 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 11 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
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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 control number."

INSTRUCTIONS FOR GENERAL DEVICE QUESTIONNAIRE

1. Answer each question by checking yes or no in the right column. 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. Question 6 is applicable only to devices recommended for class II.
6. Questions 7 & 8 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."
7. Question 9 is applicable only to devices recommended for class III.
8. Question 10 refers to restriction such as prescription use or similar limitations as to the use of the device.
9. Use this completed questionnaire to prepare the Supplemental Data Sheet. Send both forms to the address indicated in item 11.