

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: January 1, 2000
(See OMB Statement on Page 2)

PANEL MEMBER / PETITIONER		DATE
GENERIC TYPE OF DEVICE		CLASSIFICATION RECOMMENDATION
1. IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING ?		<input type="checkbox"/> YES <input type="checkbox"/> NO Go to Item 2.
2. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE IN PREVENTING IMPAIRMENT OF HUMAN HEALTH ?		<input type="checkbox"/> YES <input type="checkbox"/> NO Go to Item 3.
3. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY ?		<input type="checkbox"/> YES <input type="checkbox"/> NO Go to Item 4.
4. DID YOU ANSWER "YES" TO ANY OF THE ABOVE 3 QUESTIONS ?		<input type="checkbox"/> YES <input type="checkbox"/> NO If "Yes," go to Item 7. 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 ?		<input type="checkbox"/> YES <input type="checkbox"/> NO If "Yes," Classify in Class I. If "No," go to Item 6.
6. IS THERE SUFFICIENT INFORMATION TO ESTABLISH <i>SPECIAL CONTROLS</i> TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?		<input type="checkbox"/> YES <input type="checkbox"/> NO If "Yes," go to Item 7. If "No," Classify in Class I.
7. IS THERE SUFFICIENT INFORMATION TO ESTABLISH <i>SPECIAL CONTROLS</i> TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ? IF YES, CHECK THE SPECIAL CONTROL(S) NEEDED TO PROVIDE SUCH REASONABLE ASSURANCE. FOR CLASS II. <input type="checkbox"/> Postmarket Surveillance <input type="checkbox"/> Performance Standard(s) <input type="checkbox"/> Patient Registries <input type="checkbox"/> Device Tracking <input type="checkbox"/> Testing Guidelines <input type="checkbox"/> Other (specify) <hr/> <hr/> <hr/> <hr/>		<input type="checkbox"/> YES <input type="checkbox"/> NO If "Yes," Classify in Class II If "No," Classify in Class III
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. <input type="checkbox"/> Low Priority _____ <input type="checkbox"/> Medium Priority _____ <input type="checkbox"/> High Priority _____ <input type="checkbox"/> 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 ?		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NOT Applicable
10. FOR A DEVICE RECOMMENDED FOR CLASSIFICATION / RECLASSIFICATION INTO CLASS III, IDENTIFY THE PRIORITY FOR REQUIRING PREMARKET APPROVAL APPLICATION (PMA) SUBMISSIONS. <input type="checkbox"/> Low Priority _____ <input type="checkbox"/> Medium Priority _____ <input type="checkbox"/> High Priority _____ <input type="checkbox"/> Not Applicable _____		

11a. CAN THERE OTHERWISE BE REASONABLE ASSURANCE OF ITS SAFETY AND EFFECTIVENESS WITHOUT RESTRICTIONS ON ITS SALE, DISTRIBUTION OR USE, BECAUSE OF ANY POTENTIALITY FOR HARMFUL EFFECT OR THE COLLATERAL MEASURES NECESSARY FOR THE DEVICE'S USE ?	<input type="checkbox"/> YES <input type="checkbox"/> NO	If "Yes," go to Item 12. If "No," go to Item 11b.
11b. IDENTIFY THE NEEDED RESTRICTION(S) (If Item 11a. was checked "NO.") <input type="checkbox"/> Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device <input type="checkbox"/> Use only by persons with specific training or experience in its use <input type="checkbox"/> Use only in certain facilities <input type="checkbox"/> 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 Health and Industry Programs (HFZ-215) 1350 Piccard Drive Rockville, MD 20850		

OMB STATEMENT

Public reporting burden for this collection of information is estimated to average 1-2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS Reports Clearance Officer, Paperwork Reduction Project (0910-0138)
 Hubert H. Humphrey Building, Room 531-H
 200 Independence Avenue, S.W.
 Washington, DC 20201

(Please DO NOT RETURN this form to this address.)

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 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 except for In Vitro Diagnostic 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 11a 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.

SUPPLEMENTAL DATA SHEET

1. GENERIC TYPE OF DEVICE

2. ADVISORY PANEL

3. IS DEVICE AN IMPLANT ?

Yes

No

4. INDICATIONS FOR USE PRESCRIBED, RECOMMENDED, OR SUGGESTED IN THE DEVICE'S LABELING THAT WERE CONSIDERED BY THE ADVISORY

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5. IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE

General

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.....

Specific Hazards to Health

Characteristics or Features of Device Associated with Hazard

a.
b.
c.
d.

a.
b.
c.
d.

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

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

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9. IDENTIFICATION OF ANY NEEDED RESTRICTIONS ON THE USE OF THE DEVICE

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10. IF DEVICE IS IN 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. EXISTING STANDARDS APPLICABLE TO THE DEVICE, DEVICE SUBASSEMBLIES (Components) OR DEVICE MATERIALS (Parts and Accessories)

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 Health and Industry Programs (HFZ-215)
1350 Piccard Drive
Rockville, MD 20850

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200 Independence Avenue, S.W.
Washington, DC 20201

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INSTRUCTIONS FOR SUPPLEMENTAL DATA SHEET

1. The Supplemental Data Sheet should be prepared in conjunction with either the General Device Questionnaire or the In Vitro Diagnostic Product 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 11a of the General Device Questionnaire or 7a of the In Vitro Diagnostic Product 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 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.
7. Send this completed form and the appropriate questionnaire to the address indicated in item 12.