

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 ?

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 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 ?

YES  NO

If "Yes," Classify in Class I.  
If "No," go to Item 6.

6. IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?

YES  NO

If "Yes," go to Item 7.  
If "No," Classify in Class I.

7. IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ? IF YES, CHECK THE SPECIAL CONTROL(S) NEEDED TO PROVIDE SUCH REASONABLE ASSURANCE. FOR CLASS II.

YES  NO

If "Yes," Classify in Class II  
If "No," Classify in Class III

- Postmarket Surveillance
- Performance Standard(s)
- Patient Registries
- 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 \_\_\_\_\_

## 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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## 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.