Device Classification/ Reclassification Procedures

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Overview

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- Preamendments vs. Postamendments
- Classification/Reclassification Procedures
- Description of Device Classes
- What We Need From the Panel
- General Device Classification Questionnaire
- Supplemental Data Sheet
- What's Next

Background

- The Federal Food, Drug, and Cosmetic Act
- The Medical Device Amendments of 1976
- Safe Medical Devices Act of 1990
- FDAMA
- Classification/Reclassification
  - -Identification of Risks
  - -Designation of Controls to Mitigate Risks
  - -Generic Type of Device
  - -Intended Use

Preamendments vs. Postamendments Devices

The act divided the arena of medical devices into either:
-Preamendments Devices or
-Postamendments Devices

Depending on when the devices were introduced into commercial distribution

Classification of Preamendments Devices

Preamendments Devices are classified after FDA has:

- Received a recommendation from a device Classification Panel:
- Any such recommendation shall contain:
  -a summary of the reasons for the recommendation
  -a summary of the data upon which the recommendation is based , and

Classification of Preamendments Devices (cont.)

- An identification of the risks to health (if any) presented by the device with respect to which petition was filed
- Published the Panel's recommendation for comment, along with a PR classifying the device; and
- Published a FR classifying the device

Reclassification of Preamendments Devices

FDA may reclassify a preamendments device:

- in a proceeding that parallels the initial classification proceeding
- based upon "new information" developed as a result of reevaluation of data before FDA originally classified or not presented, available, or developed at that time

Classification of Postamendments Devices

- Postamendments devices are automatically classified into Class III
- Those devices remain in Class III and require premarket approval, unless and until
  - -the device is reclassifed into Class I or II or
  - -FDA issues an order finding the device to be SE to a predicate device that does not require premarket approval

Classification of Postamendments Devices (cont.)

- The agency determines whether new devices are SE to previously offered devices by means of premarket notification procedures in section 510(k) of the Act and Part 807 of the regulations.

Reclassification of Postamendments Devices

- May be initiated by either:
- FDA or
- the manufacturer or importer of a device by submitting a reclassification petition
- If reclassification is initiated by a petition FDA may, for good cause shown, refer the petition to a device classification panel.
- If referred to a Panel, the Panel shall make a recommendation to FDA respecting the petition

Description of Classes

Class I

1. Devices for which general controls are sufficient to provide reasonable assurance of the safety and effectiveness of such devices.

Description of Classes (cont.)

General controls include:
- -prohibition against adulterated or misbranded devices
- -premarket notification (510(k)) requirements
- -banned devices
- -GMPs — out of date term
- -Registration of manufacturing facilities
- -listing of device types
- -record keeping
- -repair, replacement, refund

Description of Classes (cont.)

2. Devices for which general controls and special controls are insufficient to provide reasonable assurance of such devices, but devices:
   -are not life-sustaining or life-supporting;
   -are not of substantial importance in preventing impairment of human health; and
   -do not present a potential unreasonable risk of illness or injury

Description of Classes (cont.)

Class II

1. Devices which cannot be classified into Class I because general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of such devices but
2. For which there is sufficient information to establish special controls to provide such assurance:

Description of Classes (cont.)

Special Controls include:

- Performance Standards (discretionary, voluntary national or international standard, recognized by rulemaking
- Postmarket Surveillance either:
  -Required (permanent implants the failure of which can cause serious adverse health consequences or death, life sustaining or life supporting, presents a serious risk to human health

Description of Classes (cont.)

Discretionary if FDA determines it is necessary to protect public health or provide safety and effectiveness data

- Patient Registries
  - -Requires information for : Traceablility and/or collection of information on device usage, adverse experiences and reliablity

Description of Classes (cont.)

- Development and dissemination of guidelines/guidances
  - -may require clinical data on a 510(k)
  - -may address labeling content regarding indications for use, instructions for use, contraindications, warnings, precautions and adverse effects
- Design Controls — Phil lately is trying to get away from the

Description of Classes (cont.)

- Recommendations and other appropriate actions
  - -Catchall provision (special labeling)
  - -Provides flexibility in establishing special controls to facilitate reclassification
- Tracking Requirements

Description of Classes (cont.)

Class III

1. Devices for which insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness of such devices and
2. Such devices are
   -life sustaining or life supporting
   -substantial importance in preventing impairment of human health; or
   -present unreasonable risk of illness or injury

New Information

Must consist of "valid scientific evidence' which includes:
-well-controlled investigations (gold standard)
-partially controlled studies;
-studies without matched controls
-well-documented case histories; and
-reports of significant human experience

What We Need From The Panel

- A recommendation for initial classification and reclassification of the devices that are the subject of this Panel session
- Recommendation should include:
  -a summary of the reasons for the recommendation;
  -a summary of the data upon which the recommendation is based, and

What We Need From The Panel (cont.)

- -An identification of the risks to health (if any) presented by the device with respect to which petition was filed.
- Limitations or exemptions for Class I
- Identification of special controls for Class II
- Priority for the call for PMAs for Class III devices
- Explanation of why premarket approval is not necessary for an implant or a life-supporting/life-sustaining device

What's Next

- Following Panel recommendations, FDA will:
- make a decision on the appropriate class
- Publish a PR or notice of panel recommendation to classify/reclassify these devices
- Review all comments; and
- Publish a FR notice classifying/reclassifying these devices

GENERAL CONTROLS: CLASS I

Registration	Banned Devices
Record-keeping	510(k) Submissions
Good Manufacturing Practices	Restrictions
Prohibition of adulterated or misbranded devices	

SPECIAL CONTROLS: CLASS II

Performance standards	Guidelines
Voluntary standards	Guidance Documents
Postmarket surveillance	Patient registries
User information-checklists	Subject to 510(k)*
Patient information and education	Design Controls**

VALID SCIENTIFIC EVIDENCE: CLASS III

Probable benefit to health outweighs any probable risk of injury or illness. Use of device will provide clinically significant results

* Can be exempt as a Class II due to FDAMA
** Applies to a few Class I devices

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VALID SCIENTIFIC EVIDENCE: CLASS III

Probable benefit to health outweighs any probable risk of injury or illness.
Use of device will provide clinically significant results

* Majority exempt subject to limitations
** Can be exempt as a Class II due to FDAMA
*** Applies to a few Class I devices

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

IERIC 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. ☐ Postmarket Surveillance ☐ Performance Standard(s) ☐ Patient Registries ☐ Device Tracking ☐ Testing Guidelines ☐ Other (specify) _____	☐ YES ☐ 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. ☐ 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 _____		

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 ?	☐ YES ☐ 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.")* ☐ 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 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.

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

SUPPLEMENTAL DATA SHEET

FORM APPROVED: OMB NO. 0910-0138
EXPIRATION DATE: January 1, 2000
(See OMB Statement on Page 2)

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

5. IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE

General

Specific Hazards to Health	Characteristics or Features of Device Associated with Hazard
a.	a.
b.	b.
c.	c.
d.	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, EXPLAI FULLY, THE REASONS FOR THE LOWER CLASSIFICATION WITH SUPPORTING DOCUMENTATION AND DATA

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

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

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 form 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.