

DEVICE CLASSIFICATION PROCEDURES

I. BACKGROUND

The Medical Device Amendments of 1976 and the Safe Medical Device Act of 1990 (SMDA) bases the classification and reclassification of pre-Amendments devices upon the level of regulatory control necessary to provide a reasonable assurance that a device is safe and effective for its intended use. Section 513(a) of the Act defines three classes of devices. A device should be placed in the lowest class whose level of control will provide a reasonable assurance of safety and effectiveness. Only preamendments devices, which at present are preamendments devices overlooked by the original classification panels, can be classified. Any device classified by the original classification panels or by statute can be reclassified. Class is determined by generic device, i.e., color change thermometers in general rather than a specific model, and intended use. Intended use includes indications for use, the intended effect, the condition or disease diagnosed or treated, the specific or target population, and any restrictions on use i.e., professional only. Intended use is the critical element for classification, determination of "substantial equivalence" (510(k)), and premarket approval.

II. DESCRIPTION OF CLASSES

Class I includes devices for which general controls alone are sufficient to assure safety and effectiveness for their intended use. General controls include Good Manufacturing Practices (GMP's), registration and listing, record - keeping, restrictions as to use, sale or distribution, prohibition of adulterated or misbranded devices, and prohibition of banned devices. Class I devices are subject to 510(k) requirements unless exempt.

Class II now includes devices for which general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls including performance standards, voluntary standards including those promulgated by groups such as AAMI or HIMA, postmarket surveillance, patient registries, guidelines (including guidelines for the submission of clinical data in premarket notification submissions, known as 510(k)s), recommendations, user checklists, and other appropriate actions. A device can be classified into Class II when enough is known about the indications for use, design, mode of operation, material composition, risk vs benefit, and the safety and effectiveness of the device. Both Class I and Class II devices are subject to the premarket notification process (510(k)).

Devices are regulated in Class III if insufficient information exists to assure that general controls (Class I) and special controls (Class II) provide reasonable assurance of safety and effectiveness, and if the devices are those represented to be

life sustaining or life supporting, or for a use which is of substantial importance in preventing impairment of human health or present potential unreasonable risk of illness or injury. Generally, implanted devices have been placed in Class III unless a lower class can be justified by sufficient information to promulgate special controls or a performance standard. New post-enactment devices, including devices determined to be not substantially equivalent, are automatically placed in class III and must have approved Premarket Approval Applications. Pre-Amendment Class III devices are regulated by the submission of 510(k)s until Premarket Approval Applications are called for by 515(b) regulation. The same considerations as to class apply to the reclassification of Preamendments devices or unclassified preamendments devices which were overlooked by the original classification panels.

CLASSIFICATION PROCEDURES

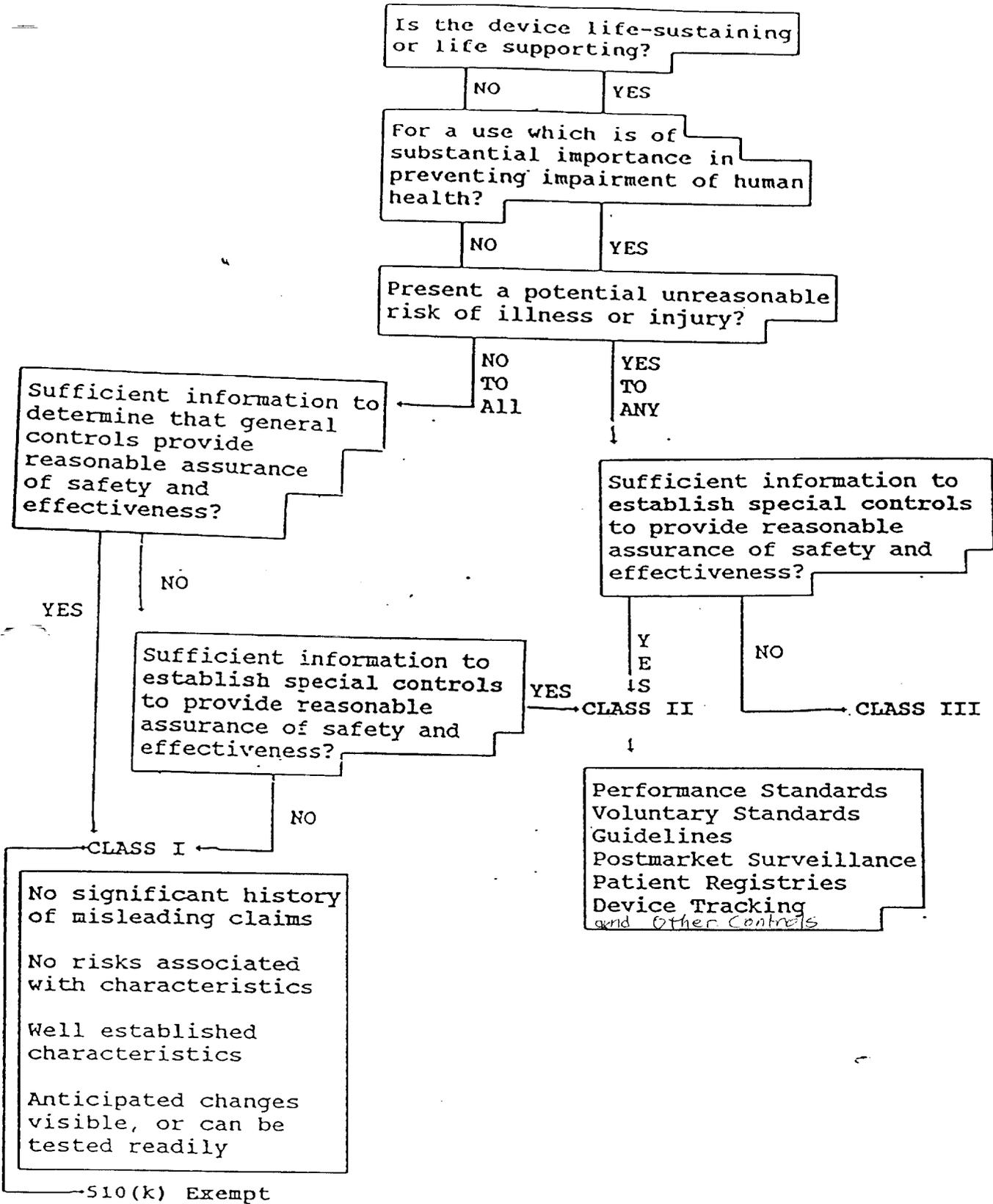
1. A Panel recommendation is required for the initial classification of a device. The branch should prepare a packet of information, obtained from a literature search and any existing 510(k)s, to facilitate the panel's decision making. The branch should supply a working generic description and name of the device, state the intended use of the device, identify the benefits of the device, delineate the risks (associate risks with the device properties or device performance), and determine which risks can be addressed by general controls or by general and special controls. Industry input could be solicited at this stage.
2. At an open public meeting a Panel makes a recommendation for a class (I or II, or III) for a device, which will include an exemption for class I devices, specified special controls for class II devices, and priority for a performance standard and the call for premarket approval applications (PMAs).
3. Subsequently, ODE makes a decision on the appropriate class, taking into account the Panel's recommendation. There is no proscribed time for this decision, either in the Act or in the CFR. The length of time for any FDA classification activity depends upon the workload of the branch involved in the procedure. Some classification recommendations made in 1990 have yet to be proposed.
4. The Agency publishes a proposed rule to reclassify and report of the Panel's recommendation in the Federal Register. The proposed rule includes the information which supports the classification. A comment period can be a minimum of 60 days, but is more typically 75 days and can be extended to 90

days.

5. Once the comment period has ended, FDA reviews all of the comments and publishes a final rule which includes FDA's responses to the comments received. Preparation of the final rule can take a minimum of a month, but typically takes a year. The final rule, i.e. the classification, usually becomes effective 30 days after the date of publication of the final rule.
6. When a device is classified into class III, FDA cannot call for PMAs for thirty months after publication of the final rule. A high-priority class III device should be the subject of a 515(b) procedure soon after the 30 months have elapsed. A request for reclassification of a device can be submitted at any time. The Act states that petitions should be filed within 45 days and acted upon within 180 days. Reclassification petitions have taken from 1 to 9 years to complete.
7. At any time after 30 months, FDA may call for PMAs following the procedures included in section 515(b) of the Act. The proposed rule lists the information which will be required by FDA in a PMA, allows a comment period, and affords an opportunity for submission of a reclassification petition as described in CFR 860.123. A reclassification petition received within 15 days of the date of publication of the proposed rule must either be denied in the Federal Register in 60 days or be the subject of a reclassification procedure initiated within 60 days.
8. A reclassification petition received in response to a 515(b) proposed rule must receive a panel recommendation. The panel can either approve or disapprove the petition. The panel can approve the petition and also recommend a lower class, i.e. class I rather than class II, than that requested by the petitioner.
9. If no reclassification petitions are submitted in response to the proposed rule, a final rule, included FDA's response to any comments received is published in the Federal Register requiring submission of PMAs by 90 days from publication of the final rule. FDA feels that the 30 months elapsed from the date of publication of the final classification rule is adequate notice for sponsors of PMAs.
10. Reclassification procedures will be addressed in a separate document.

Melpomeni K. Jeffries
Reclassification/classification coordinator
August 17, 1995

CLASSIFICATION OF MEDICAL DEVICES



CLASS II:

GENERAL CONTROLS:

SPECIAL CONTROLS:

PERFORMANCE STANDARDS

POSTMARKET SURVEILLANCE

PATIENT REGISTRIES

GUIDELINES

GUIDANCE DOCUMENTS

PATIENT INFORMATION AND EDUCATION

SUBJECT TO 510(k)

*Other. Voluntary Standards
Labeling*

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)

APPLICANT 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)

514(b) - Federal Std.

Patient Registries

Device Tracking

Testing Guidelines

Other (specify)

Voluntary Std.

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 ?	<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)

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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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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.