This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

CHANGES IN DEVICE CLASSIFICATION

The Act contains provisions for changing the classification of a device. Changes in classification are based on FDA's receipt of new information about a device.

FDA may, on its own initiative or in response to a petition by an interested party (including manufacturers), change a device's classification by regulation. The FDA may also revoke any regulation or requirement under Section 514 (Performance Standards) or 515 (Premarket Approval) that pertains to the device. The sections of the Act that apply to changing classification are 513(e), 513(f), 514(b), 515(b)(2) and 520(l)(1).

A manufacturer who wishes to have a device reclassified to a lower class must convince the FDA that the less stringent class requirements will be sufficient to provide reasonable assurance of safety and effectiveness. If the manufacturer's petition requests that the device be moved from Class III to Class II, the petition must also include information to demonstrate that sufficient information exists for developing a performance standard to reasonably assure FDA that the device is safe and effective for its intended use(s).

Once FDA has determined that a classification petition contains no deficiencies that would preclude reaching a decision on it, the petition is referred to an appropriate classification advisory committee for review and recommendation to approve or deny. The committee's recommendation is then published in the FEDERAL REGISTER for comment.

After FDA has completed its review of the comments, it notifies the petitioner by letter whether the petition has been denied or approved. In the case of an appropriate petition, an order classifying the device into Class I or II will be published in the FEDERAL REGISTER.

Petitions for reclassification should be sent directly to the Food and Drug Administration, Document Mail Center (HFZ-401), 5600 Fishers Lane, Rockville, Maryland 20857. The outside of the envelope should be clearly marked with the section of the law under which the petition is being submitted: for example, "513(e) Petition" or other applicable section. The petition and five copies should be submitted on standard size paper.

After final classification is completed, all types of petitions submitted to reclassify a device should include the following information:

- o generic group of devices to which the petition is applicable:
- o specific action that is being requested by the petition (e.g., "It is requested that devices(s) be reclassified from Class III to Class II."):
- o completed supplementary data sheets:
- o completed classification questionnaire:
- o full statement of reasons and supporting data demonstrating why the device should not be continued in its present classification and how the proposed reclassification will provide reasonable assurance of safety and effectiveness: and
- o a summary of new information used to support the petition, if that petition is based on new information under Sections 513(e), 514(b), or 515(b) of the Act.

For information and guidance on classification and reclassification, contact:

- o Office of Device Evaluation
  Investigational Device Exemption Staff, HFZ-403
  (301) 427-8162

- o Division of Small Manufacturers Assistance, HFZ-220
  (301) 443-6597 or 800 638-2041

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*See following pages for classification questionnaire form and supplementary data sheets.

(b) A regulation or an order classifying or reclassifying a device into class I will specify which requirements, if any, of sections 510, 519, and 520(f) of the act the device is to be exempted from, together with the reasons for such exemption.

(c) The Commissioner will grant exemptions under this section only if the Commissioner determines that the requirements from which the device is exempted are not necessary to provide reasonable assurance of the safety and effectiveness of the device.

Subpart C—Reclassification

§ 860.120 General.

(a) Sections 513(e) and (f), 514(b), 515(b), and 520(l) of the act provide for reclassification of a device and prescribe the procedures to be followed to effect reclassification. The purposes of Subpart C are to:

(1) Set forth the requirements as to form and content of petitions for reclassification;

(2) Describe the circumstances in which each of the five statutory reclassification provisions applies; and

(3) Explain the procedure for reclassification prescribed in the five statutory reclassification provisions.

(b) The criteria for determining the proper class for a device are set forth in § 860.3(c). The reclassification of any device within a generic type of device causes the reclassification of all substantially equivalent devices within that generic type. Accordingly, a petition for the reclassification of a specific device will be considered a petition for reclassification of all substantially equivalent devices within the same generic type.

(c) Any interested person may submit a petition for reclassification under section 513(e), 514(b), or 515(b). A manufacturer or importer may submit a petition for reclassification under section 513(f) or 520(l).

§ 860.123 Reclassification petition: Content and form.

(a) Unless otherwise provided in writing by the Commissioner, any petition for reclassification of a device, regardless of the section of the act under which it is filed, shall include the following:

(1) A specification of the type of device for which reclassification is requested;

(2) A statement of the action requested by the petitioner, e.g., "It is requested that — device(s) be reclassified from class III to a class II";

(3) A completed supplemental data sheet applicable to the device for which reclassification is requested;

(4) A completed classification questionnaire applicable to the device for which reclassification is requested;

(5) A statement of the basis for disagreement with the present classification status of the device;

(6) A full statement of the reasons, together with supporting data satisfying the requirements of § 860.7, why the device should not be classified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device;

(7) Representative data and information known by the petitioner that are unfavorable to the petitioner's position;

(8) If the petition is based upon new information under section 513(e), 514(b), or 515(b) of the act, a summary of the new information;

(9) Copies of source documents from which new information used to support the petition has been obtained (attached as appendices to the petition).

(b) Each petition submitted pursuant to this section shall be:

(1) Addressed to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Standards and Regulations (HFZ-84), 5600 Fishers Lane, Rockville, MD 20857;

(2) Marked clearly with the section of the act under which the petition is being submitted, i.e., "513(e)," "513(f)," "514(b)," "515(b)," or "520(l) Petition";

(3) Bound in a volume or volumes, where necessary; and

(4) Submitted in an original and two copies.

[43 FR 32993, July 28, 1978, as amended at 49 FR 14505, Apr. 12, 1984; 53 FR 11253, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990]

§ 860.125 Consultation with panels.

(a) When the Commissioner is required to refer a reclassification petition to a classification panel for its recommendation under § 860.134, or is required, or chooses, to consult with a panel concerning a reclassification petition, such as under § 860.130, § 860.132, or § 860.136, the Commissioner will distribute a copy of the petition, or its relevant portions, to each panel member and will consult with the panel in one of the following ways:

(1) Consultation by telephone with at least a majority of current voting panel members and, when possible, nonvoting panel members;

(2) Consultation by mail with at least a majority of current voting panel members and, when possible, nonvoting panel members; and

(3) Discussion at a panel meeting.

(b) The method of consultation chosen by the Commissioner will depend upon the importance and complexity of the subject matter involved and the time available for action. When time and circumstances permit, the Commissioner will consult with a panel through discussion at a panel meeting.

(c) When a petition is submitted under § 860.134 for a post-enactment, not substantially equivalent device ("new device"), in consulting with the panel the Commissioner will obtain a recommendation that includes the information described in § 860.84(d). In consulting with a panel about a petition submitted under § 860.130, § 860.132, or § 860.136, the Commissioner may or may not obtain a formal recommendation.

§ 860.130 General procedures under section 513(e) of the act.

(a) Section 513(e) of the act applies to reclassification proceedings under the act based upon new information.

(b) A proceeding to reclassify a device under section 513(e) may be initiated:

(1) On the initiative of the Commissioner alone;

(2) On the initiative of the Commissioner in response to a request for change in classification based upon new information, under section 514(b) or 515(b) of the act (see § 860.132); or

(3) In response to the petition of an interested person, based upon new information, filed in accordance with § 860.123.

(c) The rulemaking procedures in § 10.40 of this chapter apply to proceedings to reclassify a device under section 513(e), except that the Commissioner may secure a recommendation with respect to a proposed reclassification from the classification panel to which the device was last referred. The panel will consider a proposed reclassification submitted to it by the Commissioner in accordance with the consultation procedures of § 860.125. Any recommendation submitted to the Commissioner by the panel will be published in the FEDERAL REGISTER when the Commissioner promulgates a regulation under this section.

(d) Within 180 days after the filing of a petition for reclassification under this section, the Commissioner, by order published in the FEDERAL REGISTER, will either deny the petition or give notice of his intent to initiate a change in the classification of the device.

(e) If a device is reclassified under this section, the regulation effecting the reclassification may revoke any performance standard or premarket approval requirement that previously applied to the device but that is no longer applicable because of the change in classification.

(f) A regulation under this section changing the classification of a device from class III to class II may provide that such classification will not take effect until the effective date of a performance standard for the device established under section 514 of the act.

§ 860.132 Procedures when the Commissioner initiates a performance standard or premarket approval proceeding under section 514(b) or 515(b) of the act.

(a) Sections 514(b) and 515(b) of the act require the Commissioner to provide, by notice in the FEDERAL REGIS-

TER, an opportunity for interested parties to request a change in the classification of a device based upon new information relevant to its classification when the Commissioner initiates a proceeding either to develop a performance standard for the device if in class II, or to promulgate a regulation requiring premarket approval for the device if in class III. In either case, if the Commissioner agrees that the new information warrants a change in classification, the Commissioner will publish in the FEDERAL REGISTER notice of the Commissioner's intent to initiate a proceeding under section 513(e) of the act and § 860.130 to effect such a change.

(b) The procedures for effecting a change in classification under sections 514(b) and 515(b) of the act are as follows:

(1) Within 15 days after publication of the Commissioner's notice referred to in paragraph (a) of this section, an interested person files a petition for reclassification in accordance with § 860.123.

(2) The Commissioner consults with the appropriate classification panel with regard to the petition in accordance with § 860.125.

(3) Within 60 days after publication of the notice referred to in paragraph (a) of this section, the Commissioner, by order published in the FEDERAL REGISTER, either denies the petition or gives notice of his intent to initiate a change in classification in accordance with § 860.130.

§ 860.134 Procedures for "new devices" under section 513(f) of the act.

(a) Section 513(f)(2) of the act applies to reclassification proceedings initiated by a manufacturer or importer for reclassification of a device currently in class III by operation of section 513(f)(1) of the act. This category includes any device that is to be first introduced or delivered for introduction into interstate commerce for commercial distribution after May 28, 1976, unless:

(1) It is substantially equivalent to another device that was in commercial distribution before that date and had not been regulated before that date as a new drug; or

(2) It is substantially equivalent to another device that was not in commercial distribution before such date but which has been classified into class I or class II; or

(3) The Commissioner has classified the device into class I or class II in response to a petition for reclassification under this section.

The Commissioner determines whether a device is "substantially equivalent" for purposes of the application of this section. If a manufacturer or importer believes that a device is not "substantially equivalent" but that it should not be in class III under the criteria in § 860.3(c), the manufacturer or importer may petition for reclassification under this section. A manufacturer or importer who believes that a device is "substantially equivalent" and wishes to proceed to market the device shall submit a premarket notification in accordance with Part 807 of this chapter. After considering a premarket notification, the Commissioner will determine whether the device is "substantially equivalent" and will notify the manufacturer or importer of such determination in accordance with Part 807 of this chapter.

(b) The procedures for effecting reclassification under section 513(f) of the act are as follows:

(1) The manufacturer or importer of the device petitions for reclassification of the device in accordance with § 860.123.

(2) Within 30 days after the petition is filed, the Commissioner notifies the petitioner of any deficiencies in the petition that prevent the Commissioner from making a decision on it and allows the petitioner to supplement a deficient petition. Within 30 days after any supplemental material is received, the Commissioner notifies the petitioner whether the petition, as supplemented, is adequate for review.

(3) After determining that the petition contains no deficiencies precluding a decision on it, the Commissioner refers the petition to the appropriate classification panel for its review and recommendation whether to approve or deny the petition.

(4) Within 90 days after the date the petition is referred to the panel, fol-

lowing the review procedures set forth in § 860.84(c) for the original classification of an "old" device, the panel submits to the Commissioner its recommendation containing the information set forth in § 860.84(d). A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel, if appropriate, and developed a proposed reclassification order. Preliminary panel recommendations are filed in the Dockets Management Branch upon receipt and are available to the public upon request.

(5) The panel recommendation is published in the FEDERAL REGISTER as soon as practicable and interested persons are provided an opportunity to comment on the recommendation.

(6) Within 90 days after the panel's recommendation is received (and no more than 210 days after the date the petition was filed), the Commissioner denies or approves the petition by order in the form of a letter to the petitioner. If the Commissioner approves the petition, the order will classify the device into class I or class II in accordance with the criteria set forth in § 860.3(c) and subject to the applicable requirements of § 860.93, relating to the classification of implants, life-supporting or life-sustaining devices, and § 860.95, relating to exemptions from certain requirements of the act.

(7) Within a reasonable time after issuance of an order under this section, the Commissioner announces the order by notice published in the FEDERAL REGISTER.

§ 860.136 Procedures for transitional products under section 520(l) of the act.

(a) Section 520(l)(2) of the act applies to reclassification proceedings initiated by a manufacturer or importer for reclassification of a device currently in class III by operation of section 520(l)(1) of the act. This section applies only to devices that the Food and Drug Administration regarded as "new drugs" before May 28, 1976.

(b) The procedures for effecting reclassification under section 520(l) are as follows:

(1) The manufacturer or importer of the device files a petition for reclassification of the device in accordance with § 860.123.

(2) Within 30 days after the petition is filed, the Commissioner notifies the petitioner of any deficiencies in the petition that prevent the Commissioner from making a decision on it, allowing the petitioner to supplement a deficient petition. Within 30 days after any supplemental material is received, the Commissioner notifies the petitioner whether the petition, as supplemented, is adequate for review.

(3) The Commissioner provides the petitioner an opportunity for a regulatory hearing conducted in accordance with Part 16 of this chapter.

(4) The Commissioner consults with the appropriate classification panel with regard to the petition in accordance with § 860.125.

(5) Within 180 days after the petition is filed (where the Commissioner has determined it to be adequate for review), the Commissioner, by order in the form of a letter to the petitioner, either denies the petition or classifies the device into class I or class II in accordance with the criteria set forth in § 860.3(c).

(6) Within a reasonable time after issuance of an order under this section, the Commissioner announces the order by notice published in the FEDERAL REGISTER.

PART 861—PROCEDURES FOR PERFORMANCE STANDARDS DEVELOPMENT

Subpart A—General

Sec.

Subpart B—Procedures for Performance Standards Development and Publication

CLASSIFICATION QUESTIONNAIRE

In § 860.3(f), the Commissioner is also proposing a definition of "classification questionnaire." In the May 19, 1975 notice concerning classification, an 18-question classification logic system was included which has since been conformed to the classification provisions in the act as enacted. The classification questionnaire is intended only to assist in determining the proper device classification by facilitating the application of the criteria in proposed § 860.3(c).

Besides the 18-question classification questionnaire that will be used for most devices, a seperate six-question questionnaire has been developed for use in classifying in vita diagnostic products, which are a kind of device. This seperate questionnaire is desirable because of the different characteristics of invitro diagnostic products.

The current classification questionnaires read as follows:

GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE

Question 1: Is the device custom made?

Answer: Yes—Go to question 2. No—Go to question 3.

Question 2: Although the device is custom made, can standards be applied?

Answer: Yes or No—Go to question 17.

Question 3: Is the device life-sustaining or life-supporting?

Answer: Yes—Go to question 5. No—Go to question 4.

Question 4: Is the device or diagnostic information derived from use of the device potentially hazardous to life or good health when properly used?

Answer: Yes—Go to question 5. No—Go to question 7. Do not know—Go to question 5.

Question 5. Is the device of such a nature that: (a) Sufficient scientific and medical data exist from which adequate standards governing the device safety and efficacy could not be established; and, (b) development and application of such a standard would be adequate to control the device?

Answer: Yes—Go to question 7. No—Go to question 6. Do not know—Go to question 6.

Question 6: Is the device currently in use and marketed in the United States?

Answer: Yes or No—Go to question 7.

Question 7: When the device is used, is it remote from the body? (Remote means no physical or energy connection to the body, nor is it used as a part of a delivery system for gases, fluids, or other materials to or from the body.)

Answer: Yes—Go to question 14. No—Go to question 8. (Device is not remote if it is: (1) Associated with the body through some form of energy transmission or conduction or used as a delivery system for gases, fluids or other materials to or from the body; (2) used on surface of the body; (3) used in contact with an internal body surface or cavity or used as a short-term implant; and/or (4) used as a long-term implant that is desgned to be inserted into the body and reside indefinitely within the body.) Do not know—Go to question 8.

Question 8: Is the device powered by a non-manual external or internal source (such as electrical, pneumatic, nuclear, etc.)?

Answer: Yes—Go to question 9. No—Go to question 13.

Question 9: Will the use of the device or failure of power or device power source present a potential hazard to the patient?

Answer: Yes or No—Go to question 10. Do not know—Go to question 10.

Question 10: Does the device emit and/or inject any form of energy to or into the body?

Answer: Yes—Go to question 11. No—Go to question 13.

Question 11: Have the energy levels used been shown to be acceptable?

Answer: Yes or No—Go to question 12.

Question 12: Will malfunction of the device result in safe energy levels?

Answer: Yes or No—Go to question 13. Do not know—Go to question 13.

Question 13: Does the device use material for contact with the body which is generally acceptable or has known and acceptable properties which can be provided with no additional control requirements?

Answer: Yes or No—Go to question 14. Do not know—Go to question 14.

Question 14: Does the device have any known hazards, limitations, or shortcomings which can be avoided by promulgation of Federal regulations applicable to the device in question?

Answer: Yes or No—Go to question 15.

Question 15: If the device performs some measurement function, should the accuracy, reproducibility, or limitations of the information supplied be clearly indicated to the user by appropriate labeling, instructions, or precautions?

Answer: Yes—Go to question 16. Special labeling may be required to indicate the accuracy, reproducibility, or limitations of the information supplied by the device. No—Go to question 16.

Question 16: Does the device have performance characteristics which should be maintained at a satisfactory level, such level having general agreement among the user groups?

Answer: Yes or No—Go to question 17.

Question 17: Is the device used with other devices in such a way that the system in which it is used can be hazardous if the system is not assembled, used, or maintained in a satisfactory fashion?

Answer: Yes or do not know—Special labeling may be required to warn the user that the device may be hazardous if the system is not assembled, used, or maintained in a satisfactory fashion.

Question 18: Is the device potentially hazardous to the fetus or the gonads when properly used?

Answer: Yes or do not know—The device will be reviewed by the obstetrical and gynecological panel and the classifying panel jointly for further classification.

IN VITRO DIAGNOSTIC PRODUCT CLASSIFICATION QUESTIONNAIRE

Question 1: Is the in vitro diagnostic product or information derived from the use of the diagnostic product potentially hazardous to life, health, or well being when put to its intended use?

Answer: Yes or No—Go to question 2.

Question 2: Are general controls (class I), adequate to ensure the safe and effective use of the product?

Answer: Yes—Go to question 5. No—Go to question 3.

Question 3: Considering the nature and complexity of the product and available scientific and medical data, is it possible to develop a standard or set of standards to control the safety or effectiveness of the diagnostic product?

Answer: Yes—Go to question 5. No—Go to question 4.

Question 4: Can some components or characteristics of the product be adequately controlled by standards? Specify.

Answer: Yes or No—Go to question 5.

Question 5: Are there any special problems relating to the product that require special attention: (For example, special labeling requirements including areas such as warnings)? Identify the problem.

Answer: Yes—Go on to question 6.

Question 6: Does the product require some form of certification? Define.

The Commissioner is also proposing a definition of "supplemental data sheet." The supplemental data sheet has been prepared to gather together and report information relevant to the classification and reclassification of a device and is to be used by classification panels and may be used in petitions for reclassification to satisfy the requirements of proposed § 860.123(a)(3).

The classification questionnaire and supplemental data sheet may be changed from time to time as the agency gains experience in their use. Current copies may be obtained from the Classification Coordinator (HFK-400), Bureau of Medical Devices, Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910.

The proposed definition of "generic type of device" is intended to identify those device products that are so similar that they can be considered the same type of device for purposes of applying the regulatory controls provided by the act. The definition of "generic type of device" is important for proposed Part 860 because actions taken on both classification and reclassification apply to all devices which are within the same generic type of device and which are substantially equivalent. This approach is necessary to enable the Commissioner to provide similar regulatory treatment for essentially identical products of different manufacturers or importers.

Confidentiality and use of data and information submitted in connection with classification and reclassification. Proposed § 860.5 governs the availability for public disclosure and the use by the Commissioner of any data and information submitted to the classification panels or the Commissioner in connection with the classification and reclassification of devices under proposed Part 860.

The policy expressed in § 860.5(c) concerning the availability for public disclosure of safety and effectiveness data submitted in connection with clasification codifies rules announced in the May 19, 1975, notice on interim medical device classification procedures and is consistent with the legislative history of the amendments (Ref. 1, at pp. 48-50).

CLASSIFICATION QUESTIONNAIRE FORM

Medical Device Classification System

Panel Member: _____ Date: _____

Device: _____

Use Categories: ☐ Diagnostic ☐ Monitoring ☐ Prosthetic ☐ Surgical ☐ Therapeutic ☐ Other

Regulatory Level: I. General Controls
II. Performance Standards
III. Premarket Approval

Specific device problems: Yes No

Classification System	Yes	No	Do Not Know	Regulatory Level	Question Scheme
1. Custom Made?					Yes--2 No--3
2. Custom Made: Standard?					Yes No 17
3. Life-sustaining?					Yes--5 No--4
4. Potentially hazardous to life, good health					Yes, DNK } 5 No--7
5. (a) Can standards be developed now; and (b) would standard be adequate?					Yes--7 No, DNK--6
6. Marketed in U.S.?					Yes, No } 7
7. Remote from body?					Yes--14 No, DNK } 8
8. Powered?					Yes--9 No--13
9. Failure of power: hazardous to patient?					Yes, DNK, No } 10
10. Introduce energy into body?					Yes--11 No--13
11. Acceptable energy levels?					Yes, No } 12
12. Safe energy levels if malfunction?					Yes, No, DNK } 13
13. Material regarded as safe without standard:					Yes, No, DNK } 14
14. Proscriptions needed? limitation, hazards, difficulties, problems					Yes, No } 15
15. Labeling, instructions or precautions on measurement function?					Yes, No } 16
16. Performance Standards?					Yes, No } 17
17. Special safety systems considerations?					Yes, No, DNK } 18
18. Potentially hazardous to fetus and/or gonads					Yes, DNK } To Ob-Gyn Panel
Low Density Coding Form					

Supplementary Data Sheet
Summary of Reasons for Classification

1. Device Name _____

2. Classification Panel _____

3. Is device an implant? _____

4. Indications for use prescribed, recommended, or suggested in the device's labeling that were considered by the panel _____

_____

5. Identification of any risks to health presented by device

General _____

_____

_____

	Specific Hazards to Health		Characteristic or Feature of Device Associated with Hazard
a.	_____	a.	_____
b.	_____	b.	_____
c.	_____	c.	_____
d.	_____	d.	_____

6. Recommended 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 reasons for the lower classification with supporting documentation and data

_____

_____

_____

_____

8. Summary of data including clinical experience or judgment upon which classification recommendation is based

_____

_____

_____

9. Identification of any needed restrictions on the use of the device

_____

_____

_____

10. If device is in Class I, recommend whether FDA should exempt it from:

	Justification/COMMENTS
a. Registration	a. _____
b. Records and Reports	b. _____
c. Good Manufacturing Practice	c. _____

11. Existing standards applicable to the device, device subassemblies (components), or device materials (parts and accessories)

_____

_____

_____

_____

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, EXPLAIN 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

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)*

.....

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.....

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.....

.....

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 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.

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. ☐ 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 _____		

1a. 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.
1b. 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

IN VITRO DIAGNOSTIC PRODUCT 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 IN VITRO DIAGNOSTIC PRODUCT OR INFORMATION DERIVED FROM ITS USE POTENTIALLY HAZARDOUS TO LIFE, HEALTH, OR WELL BEING WHEN PUT TO ITS INTENDED USE ?	☐ YES ☐ NO	Go to Item 2.
2. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF THE DEVICE ?	☐ YES ☐ NO	If "Yes," classify in Class I If "No,", go to Item 3.
3a. CONSIDERING THE NATURE AND COMPLEXITY OF THE PRODUCT AND THE AVAILABLE SCIENTIFIC AND MEDICAL INFORMATION, IS THERE SUFFICIENT INFORMATION TO ESTABLISH A SPECIAL CONTROL OR SET OF SPECIAL CONTROLS TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF THE DEVICE ?	☐ YES ☐ NO	If "Yes," Classify in Class II and go to Item 3b. If "No," Classify in Class III and go to Item 4a.
3b. CHECK THE SPECIAL CONTROL(S) NEEDED TO PROVIDE SUCH REASONABLE ASSURANCES *(If "YES" to Item 3a.)* ☐ Postmarket Surveillance ☐ Performance Standard(s) ☐ Testing Guidelines ☐ Device Tracking ☐ Other *(Specify)* _____	☐ YES ☐ NO	
4a. IS A REGULATORY PERFORMANCE STANDARD NEEDED TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF A CLASS II OR III DEVICE ?	☐ YES ☐ NOT Applicable	
4b. IF "YES," TO ITEM 4a., IDENTIFY THE PRIORITY FOR ESTABLISHING SUCH A STANDARD. ☐ Low Priority ☐ Medium Priority ☐ High Priority	☐ NOT Applicable	
5. 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	
6. 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		

7a. 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 8. If "No," go to Item 7b.
7b. IDENTIFY THE NEEDED RESTRICTION(S) IF ITEM 7a. IS "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):* _____		

8. 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

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Washington, DC 20201

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INSTRUCTIONS FOR IN VITRO DIAGNOSTIC 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 In Vitro Diagnostic Product Questionnaire is designed to aid in the determination of the proper class only 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. Question 1 pertains to the degree of risk of the device and can be answered broadly.

5. Questions 4b & 5 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 6 is applicable only to devices recommended for class III.

7. Question 7a refers to restrictions 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 8.