

**IN VITRO DIAGNOSTIC PRODUCT CLASSIFICATION QUESTIONNAIRE**

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 ?	<input type="checkbox"/> YES <input type="checkbox"/> 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 ?	<input type="checkbox"/> YES <input type="checkbox"/> 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 ?	<input type="checkbox"/> YES <input type="checkbox"/> 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.)	<input type="checkbox"/> YES <input type="checkbox"/> NO	
<input type="checkbox"/> Postmarket Surveillance		
<input type="checkbox"/> Performance Standard(s)		
<input type="checkbox"/> Testing Guidelines		
<input type="checkbox"/> Device Tracking		
<input type="checkbox"/> Other (Specify) _____		
4a. IS A REGULATORY PERFORMANCE STANDARD NEEDED TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF A CLASS II OR III DEVICE ?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
4b. IF "YES," TO ITEM 4a., IDENTIFY THE PRIORITY FOR ESTABLISHING SUCH A STANDARD.	<input type="checkbox"/> NOT Applicable	
<input type="checkbox"/> Low Priority		
<input type="checkbox"/> Medium Priority		
<input type="checkbox"/> High Priority		
5. 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	
6. 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		

<p>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 ?</p>	<p><input type="checkbox"/> YES    <input type="checkbox"/> NO</p>	<p>If "Yes," go to Item 8. If "No," go to Item 7b.</p>
<p>7b. IDENTIFY THE NEEDED RESTRICTION(S) IF ITEM 7a. IS "NO."</p> <p><input type="checkbox"/> Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device.</p> <p><input type="checkbox"/> Use only by persons with specific training or experience in its use.</p> <p><input type="checkbox"/> Use only in certain facilities.</p> <p><input type="checkbox"/> Other (Specify): _____</p>		
<p>8. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO:</p> <p style="text-align: center;">Food and Drug Administration Center for Devices and Radiological Health Office of Health and Industry Programs (HFZ-215) 1350 Piccard Drive Rockville, MD 20850</p>		

**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:

Department of Health and Human Services  
Food and Drug Administration  
2094 Gaither Road, (HFZ-215)  
Rockville, MD 20850

*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 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.