

CDRH PRELIMINARY INTERNAL EVALUATIONS – VOLUME I

**510(k) Working Group
Preliminary Report and Recommendations**

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Center for Devices and Radiological Health

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APPENDIX D: REVIEWER SURVEY

To assess the consistency of CDRH reviewers' interpretation and understanding of 510(k) regulations, guidance documents, and review practices, the Working Group conducted a survey of the Center's premarket reviewers and managers. The survey consisted of twenty questions related to reviewers' and managers' knowledge and opinions on a range of identified areas of concern, including many of the subgroup topics listed in Section 3.1 of this report.

Reviewer Cohort. The survey was sent by email to all reviewers in CDRH's two premarket review Offices, the Office of Device Evaluation (ODE) and the Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), and all reviewers were strongly encouraged to complete it. Out of a total of 308 reviewers, 215 reviewers took the survey, and at least 162 respondents answered each question.

Manager Cohort. Premarket review managers in ODE and OIVD also completed the survey as a separate cohort of respondents. Premarket review managers also completed the survey as a separate cohort of respondents. Out of a total of 38 managers (Branch Chiefs, Deputy Division Directors, and Division Directors) in ODE and OIVD, 21 ODE Branch Chiefs and Deputy Division Directors took the survey, and at least 13 respondents answered each question.

This Appendix provides a full listing of the survey questions and responses. Correct responses, where they exist, are listed in **bold**. For each question, "% Selected" indicates the percentage of respondents who selected a given option, among those respondents who answered that question. Note that some respondents skipped questions; therefore the total number of respondents who answered each question varies. Percentages may not sum to 100 percent due to rounding.

Question 1: In reviewing a 510(k) application, you may find the device substantially equivalent to a predicate device when the device under review has a new intended use and:

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. The same technology.	6.7% (14)	0.0% (0)
B. The same technology and appropriate bench testing.	5.2% (11)	4.8% (1)
C. The same technology and appropriate bench and clinical testing.	28.1% (59)	14.3% (3)
D. You cannot find this device SE.	60.0% (126)	81.0% (17)

Question 2: In reviewing a laser 510(k) application, the predicate device was cleared for skin resurfacing and the new device would like to add wrinkle removal in conjunction with skin resurfacing. The reviewer has determined that there are no differences in therapeutic effect; therefore this represents:

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. A new indication.	18.2% (37)	15.0% (3)
B. A new intended use.	15.3% (31)	5.0% (1)
C. The same intended use.	10.8% (22)	15.0% (3)
D. Both (A) and (C).	55.7% (113)	65.0% (13)

Question 3: In determining the intended use of the device, you would look at:

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. The Indications for Use (IFU) form.	1.0% (2)	0.0% (0)
B. Labeling submitted by the firm.	1.5% (3)	0.0% (0)
C. Statements made in the file or specific design attributes of the device.	1.0% (2)	0.0% (0)
D. Predicate device labeling.	1.0% (2)	0.0% (0)
E. (A), (B), and (C).	95.6% (196)	100.0% (21)

Question 4: You have a 510(k) under review that has the same indication for use as the predicate but involves a new technology. While most of the information provided in the 510(k) is consistent with the specified indication for use, you find a reference to an indication that suggests a new intended use. You further investigate this issue by performing a cursory review of the literature and the MDRs. You discover that this type of device is being used by the medical community primarily for this new use. You have safety concerns about how this technology can be used for this new use but not for the labeled use. The sponsor has clearly stated that the device has the same intended use as the predicate, and the labeling has no reference to this new intended use. What decision should FDA make?

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. Issue an SE decision based on the proposed labeling in the 510(k) that is silent on the new intended use.	5.5% (11)	0.0% (0)
B. Require the sponsor to add a black box warning against the new intended use of the device in the labeling before issuing an SE decision.	24.9% (50)	28.6% (6)
C. Follow the SE with Limitations process.	49.8% (100)	61.9% (13)
D. Issue an NSE decision because of how these types of devices are being used in the medical community (<i>i.e.</i> , new intended use) and you have significant doubts that the sponsor truly intends to market it for the indications they are seeking.	19.9% (40)	9.5% (2)

Question 5: When you have a different indication for use and are trying to assess whether this presents a new intended use, what information do you consider to determine if there is a new intended use that would result in an NSE decision?

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. I would need to ask the sponsor to provide clinical data to assess the differences before I can determine.	0.0% (0)	0.0% (0)
B. I would consider whether the device has a new therapeutic or diagnostic effect.	9.8% (20)	14.3% (3)
C. I would consider whether the indication raises new safety and/or effectiveness issues.	5.4% (11)	0.0% (0)
D. (B) and (C).	54.9% (112)	52.4% (11)
E. (A), (B), and (C).	29.9% (61)	33.3% (7)

Question 6: When reviewing a 510(k) for a modification to a predicate device, you need to determine which path to take on the flowchart. For the examples below, assume that the indications for use are unchanged and you get to the section of the flowchart that states, “Does New Device Have Same Technological Characteristics?” Which of the following represent a change in the technological characteristics from the predicate device to the subject device? (Select all that apply.)

Option	<u>Reviewers</u> % Selected (#)	<u>Managers</u> % Selected (#)
A. Replacing a digital x-ray detector's wired network connection with a wireless one.	83.5% (157)	95.2% (20)
B. Changing a catheter's material from silicone to polyvinyl chloride (PVC).	75.0% (141)	76.2% (16)
C. Moving a warning label from the back of an automated external defibrillator (AED) to the front of the device.	1.6% (3)	0.00% (0)
D. Adding an emergency stop button to a device.	51.1% (96)	42.9% (9)
E. A manufacturer of a central venous catheter that is sold to a distributor submits a 510(k) for the same product.	2.7% (5)	0.0% (0)
F. Updating the software in a device to run on Windows 7 instead of Windows XP.	50.0% (94)	38.1% (8)
G. Changing the recommended sterilization method for a device.	50.0% (94)	57.1% (12)
H. Adding a coating to inhibit the growth of microorganisms on the surface of the device.	93.1% (175)	85.7% (18)
I. Adding a signal processing algorithm to assess brain wave activity to an electroencephalograph (EEG).	89.9% (169)	90.5% (19)

Question 7: Once you have identified that the subject device has the same intended use and different technological characteristics that could affect the safety or effectiveness of the device, you have to determine if those technological characteristics raise any new types of questions of safety or effectiveness. Which of the examples below represent a new type of safety or effectiveness question(s)? (Select all that apply.)

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. An ultrasound device cleared for imaging of a fetus has a new feature to assess the stiffness of coronary arteries to determine if there is coronary artery disease.	87.0% (160)	85.7% (18)
B. A surgical device cleared to cut and ablate tissue using RF (radiofrequency ablation) is the predicate for a microwave thermotherapy system to necrose tissue.	71.2% (131)	52.4% (11)
C. A manual medical device such as a colonoscope is redesigned to be fully automated.	78.3% (144)	38.1% (8)
D. A class I medical device exempt from premarket notification requirements where the sponsor intends to coat this device with a drug to reduce inflammation.	91.8% (169)	90.5% (19)
E. A roller cardiopulmonary bypass blood pump (a device that uses a revolving roller mechanism to pump the blood during cardiopulmonary bypass surgery) is modified to use a centrifugal pump that uses centrifugal force to control blood flow.	59.8% (110)	47.6% (10)
F. A battery-operated powered wheelchair cleared to provide mobility to persons restricted to a sitting position is modified to add a stair-climbing capability.	79.9% (147)	52.4% (11)

Question 8: Regarding the 510(k) "Substantial Equivalence" Decision-Making Process flowchart, how difficult is it for you to make the determination that the new technological characteristics raise new types of safety or effectiveness questions?

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. Very difficult.	14.9% (28)	19.1% (4)
B. Somewhat difficult.	26.1% (49)	23.8% (5)
C. Occasionally difficult.	43.1% (81)	47.6% (10)
D. Rarely difficult.	16.0% (30)	9.5% (2)

Question 9: What percentage of the time did you find it moderately or highly difficult to obtain the studies (performance, animal, or clinical) that were necessary for you to make your SE/NSE decision?

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. Less than 10%.	21.1% (39)	42.9% (9)
B. Between 11-25%.	31.4% (58)	14.3% (3)
C. Between 26-50%.	25.4% (47)	28.6% (6)
D. Between 51-75%.	14.6% (27)	9.5% (2)
E. Greater than 75%.	7.6% (14)	4.8% (1)

Question 10: Consider the following 510(k) scenario. A sponsor submits a 510(k) seeking clearance for “Device X.” It is the same device type and has the same indications and intended use as “Predicate A,” but there are differences in technological characteristics between proposed “Device X” and “Predicate A,” and these technological differences could affect safety or effectiveness. Ordinarily, the next steps in the 510(k) decision-making process would be to determine whether the technological differences raise new types of safety or effectiveness questions, and, if the answer is no, to evaluate performance data to assess the impact of the technological differences. However, in this 510(k), the sponsor has also identified a second predicate device, “Predicate B.” This predicate is a different device type but the technological characteristics are the same as the proposed device. If you were the reviewer of this 510(k), which predicate device(s) would you use when making your SE/NSE determination for “Device X”?

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. “Predicate A” only, because it has the same intended use.	34.4% (64)	45.0% (9)
B. “Predicate A” for the intended use, and “Predicate B” for the technological comparison.	33.9% (63)	20.0% (4)
C. “Predicate B” only, because it has the same technological characteristics.	3.8% (7)	0.0% (0)
D. Neither predicate, because the sponsor needs to identify a different predicate device that has the same intended use and the same technological characteristics.	28.0% (52)	35.0% (7)

Question 11: The Awesomo device was cleared with general indications and labeling that do not specify an age range for the intended patient population or whether the device is for use in a clinical setting or at home. Which of the following changes would require a new 510(k)?

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. A revision of the labeling that specifies the device can be used for both adults and children.	1.1% (2)	9.5% (2)
B. A revision of the labeling that specifies the device can be used by a patient at home (by prescription use only).	1.6% (3)	9.5% (2)
C. A revision of the labeling that specifies the device can treat certain medical conditions.	7.5% (14)	19.0% (4)
D. All of the above.	73.1% (136)	66.7% (14)
E. (A) and (C).	16.7% (31)	19.1% (4)

Question 12: Which of the following technological device modifications could result in a new 510(k)? (Select all that apply.)

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. Extension of shelf life from 1 year to 5 years using methods described in the original 510(k).	40.1% (75)	14.3% (3)
B. Addition of a wireless communication feature.	94.7% (177)	95.2% (20)
C. Change from AC to battery power.	70.6% (132)	61.9% (13)
D. Dimensional specification changes.	56.2% (105)	47.6% (10)
E. Change in sterilization from gamma irradiation to ethylene oxide sterilization, with the same SAL (the material is not affected by the new sterilization method).	55.1% (103)	66.7% (14)

Question 13: Which submissions can be bundled? (Select all that apply.)

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. Submissions that require only one set of data (i.e., same intended use population).	82.7% (139)	95.2% (20)
B. Submissions describing a similar change >200 reprocessed devices.	39.9% (67)	47.6% (10)
C. Submissions for bedside monitors that include a number of parameters, for example heart rate, arrhythmia detection, and exercise equipment.	47.0% (79)	52.4% (11)
D. Submissions with different IFUs and populations, for procedures on different body parts.	5.4% (9)	0.0% (0)
E. Submissions that require review by several different divisions.	6.0% (10)	4.8% (1)

Question 14: What is a “bundled device” (“system”)? (Select all that apply.)

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. Device that consists of several different devices which are physically inter-connected.	67.9% (114)	61.9% (13)
B. Networked devices.	37.5% (63)	23.8% (5)
C. One submission for multiple devices with the same change across a number of similar devices.	39.9% (67)	33.3% (7)
D. Device that can contain inter-connected diagnostic and therapeutic parts.	56.0% (94)	57.1% (12)

Question 15: What constitutes a bundled submission but is not a bundled device (“system”)? (Select all that apply.)

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. Multiple devices with the same change across a number of similar devices.	72.8% (118)	76.2% (16)
B. A number of similarly designed dental implants.	49.4% (80)	52.4% (11)
C. Multiplex assay for 40 different analytes.	25.3% (41)	23.8% (5)
D. Assay for 20 different allergens that need data from the same patient population.	40.7% (66)	42.9% (9)
E. Bedside monitors that include a number of parameters, for example heart rate, arrhythmia detection, and exercise equipment.	21.0% (34)	19.1% (4)

Question 16: Which of the following devices is NOT eligible for the de novo process? (Assume there are not any unmentioned factors that make them ineligible for de novo.)

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. A device that already has a valid predicate.	13.6% (24)	19.1% (4)
B. A device that has been classified into class III by regulation.	7.3% (13)	9.5% (2)
C. A low-risk device for which there is no valid predicate.	9.6% (17)	4.8% (1)
D. (A) and (B) only.	69.5% (123)	85.7% (18)

Question 17: Which of the following are examples of special controls? (Select all that apply.)

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. Guidance document.	83.1% (147)	95.2% (20)
B. Postmarket study.	49.7% (88)	42.9% (9)
C. Patient registries.	42.4% (75)	38.1% (8)
D. Medical Device Reporting (MDR).	26.6% (47)	38.1% (8)
E. Good Manufacturing Practices.	32.8% (58)	57.1% (12)
F. Standards.	69.5% (123)	80.1% (17)
G. Device labeling recommendations.	68.4% (121)	90.5% (19)

Question 18: A 510(k) submission typically is not eligible for third-party review if it:

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. Is for a class II device that requires clinical data.	59.9% (103)	92.9% (13)
B. Is for a class I device that presents significant risk.	3.5% (6)	0.0% (0)
C. Is a Special 510(k) rather than a Traditional or Abbreviated 510(k).	8.7% (15)	0.0% (0)
D. Is for a class II device, and FDA has not issued device-specific guidance.	27.9% (48)	7.1% (1)

Question 19: According to FDA’s guidance on third-party review, which of the following statements is true?

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. Third parties normally should perform an independent review without contacting FDA for guidance.	6.5% (11)	5.0% (1)
B. Third parties should access FDA’s IMAGE system to view 510(k)s for predicate devices.	3.5% (6)	0.0% (0)
C. If a third party identifies any deficiencies in a 510(k) submission, the third party should contact the 510(k) submitter.	20.0% (34)	40.0% (8)
D. Both (A) and (C).	70.0% (119)	60.0% (12)

Question 20: Which of the following items do you believe you have the authority to use to support your premarket review? (Select all that apply.)

Option	Reviewers % Selected (#)	Managers % Selected (#)
A. MDRs.	95.1% (175)	100% (21)
B. Recalls.	89.1% (164)	95.2% (20)
C. Network signals.²⁰⁰	73.4% (135)	85.7% (18)
D. Literature.	95.7% (176)	95.2% (20)

²⁰⁰ “Network signals” refer to information from various parts of the Center that raise questions about the safety and/or effectiveness of a specific device or device type.