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Client Alert

FDA & Life Sciences Practice Group

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FDA Announces Changes Affecting 510(k) Marketing Pathway

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On January 19, 2011, FDA announced 25 actions that it intends to implement or begin implementing this year with regard to the 510(k) process (and associated action dates)—as well as 7 controversial proposals it has decided not to implement now, but intends to further consider. See FDA, 510(k) and Science Report Recommendations: Summary and Overview of Comments and Next Steps (510(k) Actions Report).[i] The actions announced are less sweeping than the 55 recommendations for the 510(k) process made by the agency's internal 510(k) Working Group and Science Task Force and released in August 2010.[ii] FDA received public comments on those recommendations and states that its actions are in most respects consistent with the comments received.[iii]

The 25 actions FDA intends to adopt and related timelines are appended at the end of this Alert.[iv] These actions fall into three broad categories: guidance development, internal/administrative actions, and programmatic/regulatory initiatives. FDA states that the actions are intended to "support[] innovation, keep[] jobs here at home, and bring[] important, safe, and effective technologies to patients quickly."[v] These goals were emphasized in a *Wall Street Journal* op-ed by President Barack Obama.[vi] In a January 19 press call, CDRH Director Jeff Shuren explained that the actions are also intended to enhance the consistency, predictability, and transparency of the Center's 510(k) practices.

While certain actions have the potential to meet FDA's stated goals, it remains to be seen whether, as executed, these actions will produce more consistency and clarity for industry, or greater burden and complexity. Additionally, some changes (*e.g.*, guidance on 510(k)s for modifications, proposed rule on submission of labeling as part of annual listing requirements, device-specific changes described below) may be likely to result in increased regulatory scrutiny and expectations. Highlights of FDA's planned actions follow.

Planned Guidance

De Novo Classification: FDA has committed to provide guidance streamlining the de novo pathway for low-risk devices that lack an appropriate predicate. During the 510(k) press call, Director Shuren emphasized that this effort is one of the chief ways in which FDA is seeking to promote the prompt availability of innovative devices. He mentioned that

the guidance may reflect actions such as simplifying the content of 510(k)s that must be submitted (and denied) as a prerequisite to de novo classification, as well as doing away with the time-consuming guidance development process for establishing special controls where applicable to a de novo device. *(Draft guidance to be developed by September 30, 2011)*

510(k) Modifications: Regarding changes to devices with an existing 510(k) clearance, FDA reports that it will clarify the types of changes for which a new 510(k) submission would or would not be expected, as well as changes eligible for a Special 510(k). *(Draft guidance to be developed by June 15, 2011).* Considering publicly reported concerns about underreporting in this regard, it will be important to see whether FDA's draft guidance clarifies longstanding expectations or creates new ones.

510(k) Paradigm, including clinical data, "intended use," multiple and split predicates: The agency plans to provide guidance on several critical topics, including, among others, when clinical data should accompany a 510(k); the appropriate use of multiple predicates (which FDA says it "strongly supports"[vii]); criteria for identifying "different questions of safety and effectiveness" as well as technological changes generally raising these questions; and characteristics that should be included in the concept of a device's "intended use." *(Draft guidance to be developed by September 30, 2011)*

With regard to multiple predicates, FDA also intends to complete (by October 31, 2011) an analysis of an apparent association between devices whose 510(k)s cited more than five predicates and a heightened rate of adverse event reports. Any determined connection would likely affect the agency's guidance on use of multiple predicates.

Notably, FDA's 510(k) Actions Report states that the agency "do[es] not intend to implement the [510(k) Working Group's] recommendation to eliminate the use of 'split predicates.'"[viii] FDA explains that this simply means the agency will no longer use the term "split predicate" (because it perceives industry confusion regarding the meaning of this term); the agency's report makes clear that it believes use of a "true split predicate" (*i.e.*, a situation where a submitter attempts to "demonstrat[e] that a new device has the same intended use as one predicate while comparing the new device's technological characteristics with a second predicate that has a different intended use"[ix]) would be "inconsistent with the 510(k) standard."[x]

Appeals: FDA intends to clarify the process for appealing CDRH decisions, including 510(k) rescission decisions *(Draft guidance to be developed by October 31, 2011)*

Internal/Administrative Changes

Improve internal expertise and knowledge sharing: FDA's plans in this area include (1) establishing a Center Science Council to, among other things, help "continuously assess the quality, consistency and effectiveness of the 510(k) program" and "periodically audit 510(k) review decisions to assess adequacy, accuracy and consistency"; (2) training CDRH staff and industry on key 510(k) concepts such as "intended use," when a 510(k) raises "different questions of safety and effectiveness," the review of devices citing multiple predicates, applying "least burdensome" principles, and the appropriate use of consensus standards; and (3) developing and leveraging the expertise of a network of outside scientific experts. Additionally, through its Center Science Council, FDA will establish an internal team of clinical trial experts to provide support and advice to CDRH staff and investigational device exemption (IDE) applicants on the design of clinical trials; however, it is not yet clear to what extent the Center Science Council will be involved in

disputes about the need for clinical data to support certain 510(k) submissions or the adequacy of the clinical data that are collected. *(Actions include posting Center Science Council Charter to FDA website by March 31, 2011; posting initial results of 510(k) audit to FDA website by June 15, 2011; developing and implementing training on 510(k) core competencies by August 31, 2011; and posting an SOP for use of external experts by September 15, 2011.)*

Programmatic/Regulatory Changes

Streamline guidance and regulation development: FDA intends to provide greater clarity, predictability, and efficiency in these processes. *(SOPs to be posted to FDA's website by July 31, 2011)*

Expedite Industry Notification of Regulatory Changes: The agency intends to adopt a standard practice of issuing "Notice to Industry" Letters to inform stakeholders when regulatory expectations (a potential example could be data expectations) change on the basis of new scientific information. FDA has noted industry's concerns that the use of these letters in lieu of guidance would "eliminat[e] the opportunity for public comment" and industry suggestions that an SOP be established to "clearly define the parameters for when and about what topics the Center would issue such letters."[xi] *(SOP to be posted to FDA website by June 15, 2011)*

Initiate rulemakings: FDA will develop regulations to address the submission of device labeling as part of the requirement for manufacturers to submit updated device listing information annually. FDA "believe[s] that periodically submitting updated labeling to CDRH would help the Center stay abreast of new information in product labeling and that periodically auditing the submitted labeling would aid the Center in assuring the quality and accuracy of device labeling."[xii] In addition, FDA will promulgate new rules to (1) implement a Unique Device Identification (UDI) system, which FDA expects to facilitate identification of device-specific problems, and (2) improve documentation of 510(k) transfers of ownership *(UDI proposed rule to be published by June 30, 2011; device labeling and 510(k) transfer proposed rules to be published by December 31, 2011)*

Hold public meetings regarding making publicly available sensitive device information: FDA's internal 510(k) Working Group and Science Task Force recommended that CDRH develop publicly available databases that would include various information about cleared devices (*e.g.*, labeling, device photographs or schematics). While this information could potentially facilitate preparation of 510(k)s, public comments expressed significant concerns about confidential or proprietary information being included in the database. FDA has committed to hold a public meeting on April 7-8, 2011, to further discuss this proposal.

Changes to be Implemented on a Case-by-Case/Device-Specific Basis

FDA has decided to move forward with certain controversial recommendations made by its internal 510(k) Working Group, although in more limited form; the agency states it will implement the following "on a case-by-case basis through device-specific guidance."[xiii] FDA has not, however, identified the specific devices that would be subject to these requirements or identified time frames for implementation; additionally, in some cases, the actions contemplated may be beyond what FDA can appropriately effectuate through guidance. Given their potential significance, these areas remain important for industry to monitor and assess as FDA moves towards implementation.

- Notification of Device Modifications: On a case-by-case basis, FDA would require manufacturers to provide regular, periodic updates of device modifications. FDA's 510(k) Actions Report "recognize[s] that

submitting all modifications for all devices could be overly burdensome for [FDA] and manufacturers, and might not be necessary to assure that new 510(k)s are submitted when appropriate for modifications to cleared devices."[xiv] According to the report, "Generally, the circumstances under which it would be most helpful to receive periodic reports of modifications are when a change is made to a higher-risk device for which the impact on safety or effectiveness is unclear; specifically, it is unclear whether or not CDRH should require the submission of a 510(k). In these cases, CDRH would want to be notified periodically that such a change was made in lieu of submitting a 510(k)."[xv]

- Report All Known Safety and Effectiveness Information: Case-by-case, FDA would require 510(k) submitters to include in their submissions "a brief description of safety and effectiveness information specific to the device to be reviewed that is *already known* to the submitter." [xvi] (Emphasis in original) FDA believes the 510(k) Working Group's original recommendation that the agency consider new regulations extending this requirement to all 510(k) submitters and all safety and effectiveness information "known to or that should be reasonably known to" each submitter "may be too broad in scope and overly burdensome."[xvii] The report does not, however, clarify what the legal basis would be for requiring selected submitters to provide all known information and, in particular, information not related to a determination of substantial equivalence.

- Provide Manufacturing Information and/or Submit to Pre-Clearance Inspections: FDA intends to develop device-specific guidance detailing when manufacturing information would be requested in 510(k) submissions. In response to industry comments, FDA notes its "agree[ment] that manufacturing process information should be provided only for a subset of higher-risk devices for which the receipt and review of such information could prevent potential safety or quality problems."[xviii] Similarly, FDA intends to provide guidance detailing the device-specific circumstances when it believes it should exercise existing statutory authority to conduct manufacturing inspections in connection with the review of a 510(k).

- Adopt Use of an "Assurance Case" Framework for 510(k) Submissions. FDA intends to institute a pilot program to study the use of an "assurance case" framework for infusion pumps. This approach would require 510(k) sponsors to structure their submissions in a manner that more stringently demonstrates the validity of predicate comparisons. Despite industry comments that this approach could substantially hinder the already-burdened review process and/or should be limited to certain higher-risk devices, FDA has stated its belief that the use of assurance cases can improve the review of 510(k)s and aid industry in identifying and addressing potential 510(k) weaknesses pre-submission. The agency advises that it "will make any assessment of the pilot program available to the public upon the program's completion and seek public input before deciding whether or not to apply an assurance case approach to other device types and, if so, which ones."[xix]

Proposals for Which Decision-Making Has Been Deferred

Not least among FDA's announcements are its decisions ***not*** to act (pending an opportunity for input by the Institute of Medicine (IOM)) on certain potentially significant and/or detrimental recommendations of the agency's internal 510(k) Working Group and Science Task Force. These proposals generated significant controversy in public comments received by FDA,[xx] and the agency announced on January 19 that it will await possible IOM input before deciding whether or to what extent to implement the recommendations. (During the media call accompanying the announcement

of FDA's planned actions, CDRH Director Shuren clarified that there is no requirement that the IOM comment on all or any of these proposals, but FDA will consider relevant IOM comments, if any. The IOM is expected to issue its own report on FDA's 510(k) process in summer 2011; the agency has not specified any timeline for further action following that report.)

Specifically, ***FDA is delaying decisions on the following controversial recommendations pending possible IOM consideration***:

- Establish device Class IIb. Under this proposal, FDA would issue guidance creating a "Class IIb" classification for devices for which clinical data, manufacturing data, and/or postmarket data would generally be needed to support clearance. While we do not yet know whether FDA will ultimately accept or reject this proposal, FDA's 510(k) Actions Report advises that, "The intent of this recommendation was not to expand the types of devices subject to clinical data requirements, but rather to place a greater onus on CDRH to identify in advance those devices for which clinical data would be required. However…[FDA] understand[s] that implementing this recommendation may have unintended consequences."[xxi]

- Seek statutory authority to expand regulation of off-label use. FDA's 510(k) Working Group recommended that FDA seek expanded statutory authority to consider off-label use when determining a device's intended use in the clearance process. FDA's 510(k) Actions Report states that this recommendation "was intended to be limited to the rare circumstance where a manufacturer seeks clearance for one use but actually intends to market the device for a different use in order to avoid having to provide data regarding the true intended use," rather than to "force industry to provide data on potential off-label uses even if the device under consideration was never intended to be used for such purposes."[xxii] FDA further acknowledges "the challenges of drafting new legislative authority narrowly tailored to the[] limited circumstances" it intended to address and thus "understand[s] it may not be feasible to implement this recommendation without inadvertently restricting the practice of medicine."[xxiii]

- Consolidate the terms "indication for use" and "intended use". Under this proposal, the agency would combine these terms and use only the term "intended use." The proposal raised the possibility that changes in indications for use could increasingly be considered to be changes in intended use necessitating additional 510(k) clearance. FDA's 510(k) Actions Report clarifies that, "The intent of this recommendation was to reduce current confusion over the terms "intended use" and "indications for use"; not to reduce the instances in which a new indication for use would still represent the same intended use. However,…we understand that implementing this recommendation may not achieve our intended goal."[xxiv]

- Define conditions disallowing device use as predicate. The 510(k) Working Group recommended that FDA consider developing guidance to describe when a device should no longer be permitted to be used as a predicate because of safety or effectiveness concerns. Public comments opposed this recommendation on grounds that any FDA guidance may exceed statutory criteria governing the types of predicates that are inappropriate for determining substantial equivalence; that disallowing the use of certain predicates would unnecessarily constrain the availability of the 510(k) pathway for otherwise eligible devices; and that such an approach would present challenges with respect to marketed products that had relied on disallowed predicates in their 510(k) submissions. In light of these comments, FDA's 510(k) Actions Report acknowledges that "implementing this recommendation may have unintended consequences."[xxv]

- Issue a regulation defining FDA's authority to rescind a 510(k). FDA has decided to await possible IOM input on this proposal in light of significant public concerns about the agency's authority and the unnecessary and duplicative nature of rescission given FDA's ability to recall or take other enforcement actions against unsafe or ineffective devices. However, the agency's 510(k) Actions Report makes clear that, notwithstanding this, FDA believes that it "ha[s] the authority to rescind a 510(k) under appropriate circumstances."[xxvi] In the January 19th press call, CDRH Director Shuren emphasized that, even pending any IOM recommendation regarding this proposal, FDA will not refrain from taking action to rescind 510(k) clearances if the agency believes such action is warranted. Dr. Shuren noted that, as referenced above, one action item FDA is proceeding to implement is guidance addressing the appeals process for 510(k) rescission decisions.

- Seek greater authority to require postmarket surveillance as a condition of clearance. In deferring decision-making on this proposal, FDA has taken note of varying concerns raised in public comments, including questions about the need for such expanded authority in light of FDA's existing authorities in this area, and anticipated deleterious effects on industry, physicians, and innovation.

- Require manufacturers to keep one unit of a device available in the clearance process. Here, FDA noted the challenges raised by industry, given that many firms do not manufacture and/or would be significantly burdened to manufacture, store, install, or calibrate a device or prototype prior to clearance.

Thoughts for Industry

In sum, the actions FDA has announced for implementation with respect to the 510(k) process are not as drastic as the agency's internal working group recommendations; however, industry should carefully review FDA's outputs as target action dates arrive to better evaluate their impact. Additionally, certain of the most controversial proposed 510(k) changes, though in abeyance for now, are still open for future decision, and FDA has not identified a specific time frame for their resolution. Further, FDA has indicated that it will move forward to implement some controversial recommendations on a case-by-case basis with respect to specific devices but has not provided key details (e.g., what types of devices will be affected and when). Accordingly, industry should continue to closely monitor FDA's actions in the 510(k) area and identify opportunities to provide input on these actions, including commenting on draft guidances and proposed rules and/or, where appropriate, seeking to be heard through the legislative process associated with reauthorizing the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). Please contact us if we can assist you with further analysis of or advice on these matters.

[i] Available at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm.

[ii] See CDRH Preliminary Internal Evaluations -- Volume I: 510(k) Working Group Preliminary Report and Recommendations and CDRH Preliminary Internal Evaluations -- Volume II: Task Force Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations (available at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm).

[iii] FDA states that the actions it has decided to implement include ones that address each recommendation that received broad support in public comments or broad support with a caveat or modification.[iii] The agency also indicates that it is reserving for further consideration, including potential consideration by the IOM between now and summer 2011, nearly half (7/15) of the recommendations for which public comments expressed significant concern.

[iv] These are reproduced from FDA and also available at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm.

[v] See FDA News Release: FDA to Improve Most Common Review Path for Medical Devices (January 19, 2011) (available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm240418.htm).

[vi] President Obama referenced FDA's planned 510(k) actions in his op-ed titled *Toward a 21st-Century Regulatory System* (Wall Street Journal, Jan. 18, 2011). In this piece, the President discussed the potential impact on innovation of a new Executive Order (Exec. Order No. 13,563 (76 Fed. Reg. 3,821) (Jan. 21, 2011)). This order requires federal agencies to assess the necessity and effectiveness of existing, significant regulations. It is not yet clear how the Executive Order may impact the actions FDA intends to take in its 510(k) action plan or how it may affect existing FDA regulations that govern the 510(k) process.

[vii] 510(k) Actions Report at 14.

[viii] Id. at 2.

[ix] Id. at 14.

[x] Id. at 14.

[xi] Id. at 7.

[xii] Id. at 9.

[xiii] Id. at 2

[xiv] Id. at 16

[xv] Id.

[xvi] Id. at 17

[xvii] Id.

[xviii] Id. at 19.

[xix] Id. at 16.

[xx] FDA reports that it received 76 public comments from "medical device companies, representatives of the medical device industry, venture capitalists, healthcare professional organizations, third-party payers, patient and consumer advocacy groups, foreign regulatory bodies, trial lawyers, and others." FDA 510(k) Actions Report at 1.

[xxi] 510(k) Actions Report at 19.

[xxii] Id. at 12.

[xxiii] Id. at 13.

[xxiv] Id. at 12.

[xxv] Id. at 13.

[xxvi] Id. at 14.

Source: FDA

PLAN OF ACTION—IMPLEMENTATION

DESCRIPTION	ACTION	PURPOSE	MILESTONE	DATE OF COMPLETION
GUIDANCE	**510(k) Modifications Guidance**	To clarify which changes do or do not warrant submission of a new 510(k) and which modifications are eligible for a Special 510(k).	Draft Guidance	June 15, 2011
	Clinical Trial Guidance	To improve the quality and performance of clinical trials.	Draft Guidance	July 31, 2011
	Evaluation of Automatic Class III Designation (De Novo) Guidance	To streamline the de novo classification process.	Draft Guidance	September 30, 2011
	Standards Guidance	To clarify the appropriate use of consensus standards.	Draft Guidance	October 31, 2011
	Appeals Guidance	To clarify the process for appealing CDRH decisions, including decisions to rescind a 510(k).	Draft Guidance	October 31, 2011
	510(k) Paradigm Guidance	To provide greater clarity regarding: 1) when clinical data should be submitted in support of a 510(k); 2) the submission of photographs or schematics for internal FDA use only; 3) the appropriate use of multiple predicates; 4) the criteria for identifying "different questions of safety and effectiveness" and technological changes that generally raise such questions; 5) resolving discrepancies between the 510(k) flowchart and the Food, Drug, and Cosmetic Act; 6) the characteristics that should be included in the concept of “intended use”; and 7) the development of 510(k) summaries to assure they are accurate and include all required information.	Draft Guidance	September 30, 2011
	Pre-Submission Interactions Guidance	To supplement available guidance on pre-IDE meetings and enhance the quality of pre-submission interactions between industry and Center staff.	Draft Guidance	November 30, 2011
	Product Code Guidance	To more consistently develop and assign unique product codes.	Draft Guidance	December 31, 2011

			MILESTONE	DATE OF COMPLETION
INTERNAL and ADMINISTRATIVE MATTERS	**Establish a Center Science Council**	To: 1) oversee the development of a business process and SOP for determining and implementing an appropriate response to new scientific information; 2) promote the development of improved metrics to continuously assess the quality, consistency and effectiveness of the 510(k) program; 3) periodically audit 510(k) review decisions to assess adequacy, accuracy and consistency; and 4) establish an internal team of clinical trial experts to provide support and advice on clinical trial design for Center staff and prospective IDE applicants.	Post Council Charter to FDA Website	March 31, 2011
			Post initial results of 510(k) audit to FDA Website	June 15, 2011
	Assess Center Staffing Needs	To formalize the Center's internal process for identifying staffing needs, and to enhance recruitment, retention, training, and professional development of review staff. To create a mechanism to assemble an experienced ad hoc team to temporarily assist with unexpected surges in workload.	Develop process for identifying, recruiting, retaining, and training needed staff	July 15, 2011
	Enhance Training	To train new Center staff on core competencies. To train Center staff and industry on**:** 1) the determination of "intended use"; 2) the determination of whether a 510(k) raises "different questions of safety and effectiveness"; 3) the review of 510(k)s that use "multiple predicates"; 4) the development and assignment of product codes; 5) the interpretation of the "least burdensome" principles; and 6) the appropriate use of consensus standards.	Develop and implement training on core competencies	August 31, 2011
	Leverage External Experts	To develop a network of external experts to appropriately and efficiently leverage external scientific expertise. Also, to assess best-practices and develop SOPs for staff engagement with external experts.	Post SOP to FDA Website	September 15, 2011
	Continue Integration and Knowledge Management	To improve knowledge management across the Center.	Complete evaluation of methods used to integrate device information into a dynamic format so that it can be more readily used by staff to make regulatory decisions	September 30, 2011

			MILESTONE	DATE OF COMPLETION
PROGRAMMATIC and REGULATORY	**Implement an "Assurance Case" Pilot Program**	To explore the use of an “assurance case” framework for 510(k) submissions.	Start pilot program	March 31, 2011
	Provide Additional Information About Regulated Products	To make device photographs available in a public database without disclosing proprietary information.	Public Meeting *	April 7 - 8, 2011 *
	Improve Collection and Analysis of Postmarket Information	To develop better data sources, methods and tools for collecting and analyzing meaningful postmarket information, and to enhance the Center’s capabilities to support evidence synthesis and quantitative decision making.	Determine system requirements and select the platform for a new adverse event database	June 30, 2011
	Establish "Notice to Industry Letters" as a Standard Practice	To clarify and more quickly inform stakeholders when CDRH has changed its regulatory expectations on the basis of new scientific information.	Post SOP to FDA Website	June 15, 2011
	Improve the IDE Process	To better characterize the root causes of existing challenges and trends in IDE decision making.	Complete program assessment	June 30, 2011
		Assess, characterize and mitigate challenges in reviewing IDE’s.		
	Implement a Unique Device Identification (UDI) System	To permit the rapid and accurate identification of devices, to facilitate and improve adverse event reporting and identification of device-specific problems.	Issue proposed regulation	June 30, 2011
	Multiple Predicate Analysis	To conduct additional analyses to determine the basis for the apparent association between citing more than five predicates and a greater mean rate of adverse event reports.	Complete analysis and make results public	October 31, 2011

			MILESTONE	DATE OF COMPLETION
PROGRAMMATIC and REGULATORY (cont.)	**Clarify and Improve Third-Party Review**	To develop a process for regularly evaluating the list of device types eligible for third-party review and to enhance third-party reviewer training.	Post SOP to FDA Website	September 30, 2011
	Streamline Guidance and Regulation Development Process	To provide greater clarity, predictability, and efficiency in the guidance and regulation development process.	Post SOPs to FDA Website	July 31, 2011
	Draft 510(k) Transfer of Ownership Regulation	To better document 510(k) transfers of ownership.	Issue proposed regulation	December 31, 2011
	Improve Medical Device Labeling	To develop an on-line labeling repository.	Public Meeting *	April 7 - 8, 2011 *
		To clarify the statutory listing requirements for the submission of labeling.	Issue proposed regulation	December 31, 2011

DESCRIPTION	ACTION	PURPOSE	MILESTONE	DATE OF COMPLETION
ISSUES TO BE REFFERRED TO THE IOM	**Rescission Authority**	To consider defining the scope and grounds for the exercise of the Center's authority to fully or partially rescind a 510(k) clearance.	IOM REPORT	SUMMER 2011
	Postmarket Surveillance Authorities	To seek greater authorities to require postmarket surveillance studies as a condition of clearance for certain devices.		
	Establish a Class IIb	To develop guidance defining "class IIb" devices for which clinical information, manufacturing information or, potentially, additional evaluation in the postmarket setting would typically be necessary to support a substantial equivalence determination.		
	Predicate Clarification	To clarify when a device should no longer be available for use as a predicate.		
	Clarify and Consolidate Regulatory Terms	To consolidate the concepts of "indication for use" and "intended use" into a single term, "intended use".		
	Device Review	To consider the possibility of requiring each 510(k) submitter to keep at least one unit of the device under review available for CDRH to access upon request.		
	Off-Label Use	To explore the possibility of pursuing a statutory amendment that would provide the agency with the express authority to consider an off-label use when determining the "intended use" of a device.		

* The April 7-8, 2011 meeting will discuss both actions.