CDRH Plan of Action for 510(k) and Science

CDRH Plan of Action for 510(k) and Science - Implementation			
Recommendation	**Purpose**	**Milestone/Deliverable**	**Completion Date**
Implement an "Assurance Case" Pilot Program	To explore the use of an "assurance case" framework for 510(k) submissions.	Start pilot program **Pilot program underway** See infusion pump website: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/default.htm	March 31, 2011
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 pre-market programs; 3) periodically audit pre-market 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 http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm249248.htm	March 31, 2011
Provide Additional Information About Regulated Products	To make device photographs available in a public database without disclosing proprietary information.	Public Meeting* http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm243829.htm	April 7, 2011
Improve Medical Device Labeling	To develop an on-line labeling repository.	Public Meeting* http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm243829.htm	April 7, 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 **System requirements determined**	June 30, 2011
Improve the IDE Process	To better characterize the root causes of existing challenges and trends in IDE decision making. Assess, characterize and mitigate challenges in reviewing IDE's.	Complete program assessment **Assessment completed**	June 30, 2011

* Both actions were discussed at the April 7, 2011.

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Recommendation	**Purpose**	**Milestone/Deliverable**	**Completion Date**
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 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259172.pdf **Superseded by "SOP - Level 1, Immediately in Effect Guidance Documents on Premarket Data Issues"** http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259172.pdf	June 15, 2011
Establish a Center Science Council	See Above.	Post initial results of 510(k) audit to FDA Website http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm259173.htm	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 **Internal SOP completed**	July 15, 2011
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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm265274.htm	July 27, 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 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM266073.pdf	July 31, 2011
Clinical Trials Guidance	To improve the quality and performance of clinical trials and the application of the least burdensome principle	Final Guidance issued November 7, 2013 Draft Guidance http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm373750.htm	August 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	Develop and implement training on core competencies **Launched Reviewer Certification Program** Press Release: http://www.fda.gov/NewsEvents/Newsroom/P	September 6, 2011

CDRH PLAN OF ACTION FOR 510(K) AND SCIENCE - IMPLEMENTATION			
RECOMMENDATION	**PURPOSE**	**MILESTONE/DELIVERABLE**	**COMPLETION DATE**
	"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.	ressAnnouncements/ucm270858.htm	
EVALUATION OF AUTOMATIC CLASS III DESIGNATION (DE NOVO) GUIDANCE	To streamline the de novo classification process.	Draft Guidance http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm273902.htm	September 30, 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 **INTERNAL ASSESSMENT COMPLETED**	October 4, 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 http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm271521.htm	October 4, 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 http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm275629.htm	October 14, 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm282958.htm	December 27, 2011
APPEALS GUIDANCE	To clarify the process for appealing CDRH decisions by external persons.	Final Guidance issued May 17, 2013 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm284651.htm	December 28, 2011 (Draft Guidance)
PRODUCT CODE GUIDANCE	To more consistently develop and assign unique product codes.	Final Guidance issued April 11, 2013 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm285317.htm	January 3 2012 (Draft Guidance)

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Recommendation	**Purpose**	**Milestone/Deliverable**	**Completion Date**
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.	Final Rule issued September 24, 2013 Issue proposed regulation https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system	July 3, 2012 (Amended November 19, 2012)
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.	Final Guidance issued February 18, 2014 Draft Guidance http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf	July 13, 2012
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**** ****Superseded by the FDASIA provision that requires FDA to establish and publish criteria to reaccredit and deny reaccreditation to third parties** **Draft Guidance** http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm339695.htm	February 15, 2013
Standards Guidance	To clarify the appropriate use of consensus standards.	Draft Guidance	**Started** Due October 31, 2011
Improve Medical Device Labeling	To clarify the statutory listing requirements for the submission of labeling.	Issue proposed regulation	**Started** Due December 31, 2011
Draft 510(k) Transfer of Ownership Regulation	To better identify 510(k) transfers of ownership.	Issue proposed regulation	**Started** Due December 31, 2011

Additional CDRH Actions Taken in Support of 510(k) and Science Report Recommendations			
Action	**Purpose**	**Milestone/Deliverable**	**Completion Date**
Analysis of Pre-market Review Times Under the 510(k) Program	To determine factors affecting total review time and the number of review cycles.	Post results of the analysis http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm263385.htm	July 19, 2011
Making Benefit-Risk Determinations in Medical Device Pre-market Review	To provide greater clarity regarding the factors FDA considers when making benefit-risk determinations during the pre-market review process.	Final Guidance issued March 28, 2012 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM296379.pdf	August 15, 2011 (Draft Guidance)
Corrective and Preventive action (CAPA) system	To assure identification and resolution of pre-market review issues. Corrective actions and, where appropriate, preventive actions, needed to correct identified issue and prevent recurrence of the problem will be recorded in a CAPA system.	Start pilot program **Pilot program underway**	October 1, 2011
International Device Regulators Forum	To establish a new forum to accelerate international medical device harmonization and convergence.	Hold preparatory meetings with other countries	February 15-17, 2011 October 6-7, 2011
		Hold first meeting of the forum http://www.imdrf.org/	February 28 – March 1, 2012
SOPs for Requesting Additional Information	To provide an SOP that clarifies the level of sign off or concurrence required for requesting additional data for premarket reviews.	Internal SOP with training to staff http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm279288.htm	November 9, 2011
Early Feasibility Medical Device Clinical Studies Guidance	To provide greater clarity regarding the development and review of Investigational Device Exemptions (IDE) applications for early feasibility studies of significant risk devices, including first-in-human studies,	Final Guidance issued October 1, 2013 Draft Guidance http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279103.pdf	November 10, 2011 (Draft Guidance)
IDE Decisions Guidance	To provide clarification regarding the types of decisions FDA may make to approve an IDE and to provide a general explanation of the reasoning and implications of those decisions. To provide an SOP that clarifies the level of sign off or concurrence required for requesting additional data for pre-market reviews.	Draft Guidance http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm279107.pdf%3Fsource%3Dgovdelivery	November 10, 2011 (Draft issued June 14, 2013)
Change in Reviewer	To establish procedures to assure greater consistency in the review of pre-market documents (e.g., IDEs, PMAs, 510(k)s) when review staff change during the review.	Internal SOP with training to staff http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm285034.htm	December 27, 2011
Innovation Pathway	To formally develop and implement the Innovation Pathway for important medical devices and apply new approaches developed to other pre-market pathways	Begin implementing Innovation Pathway 2.0 http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/InnovationPathway/default.htm	April 9, 2012

ADDITIONAL CDRH ACTIONS TAKEN IN SUPPORT OF 510(K) AND SCIENCE REPORT RECOMMENDATIONS			
ACTION	**PURPOSE**	**MILESTONE/DELIVERABLE**	**COMPLETION DATE**
TRIAGE OF PRE-MARKET SUBMISSIONS	To increase submission review efficiency and better manage the pre-market review workload. The initial management review (triage) will help determine the level of review required for each submission.	Start pilot program Pilot program underway http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm300308.htm	April 2, 2012
FOREIGN CLINICAL STUDIES	To clarify the circumstances under which we would rely on clinical studies conducted in and for other countries.	Proposed regulation http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/html/2013-04201.htm	February 25, 2013