510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device, May 17, 2013

U.S. Food & Drug Administration

The purpose of the meeting is to discuss FDA's past, present, and future policy on 510(k) Modifications with external stakeholders. FDA seeks comment from stakeholders on different options, both in the form of submissions to the docket for the Federal Register notice associated with this meeting and in discussion during the public meeting. FDA also seeks actual examples of device modifications that industry has made in order to help the Agency develop its policy. FDA expects to discuss the following options:

1. Potential use of risk management in 510(k) device modifications decisions – can FDA incorporate risk management into its policy on how to determine whether device modifications require new 510(k) submissions in a way that ensures appropriate and consistent decisions by industry and FDA staff?
2. Potential reliance on design controls activities – FDA seeks proposals for how industry and FDA could utilize design control activities such as design verification and validation to ensure that device modifications are appropriately evaluated prior to marketing.
3. Potential use of critical specifications – FDA seeks proposals on whether it could incorporate the use of critical specifications in its policy on how to determine whether devices modifications require new 510(k) submissions in a way that ensures appropriate and consistent decisions by industry and FDA staff.
4. Potential risk-based stratification of medical devices for 510(k) modification purposes – FDA seeks input on the practicality of stratifying devices that require 510(k)s by risk, where lower risk devices would not require 510(k)s for most modifications, if those modifications are part of periodic reports submitted to the Agency.
5. Potential periodic reporting – FDA seeks comments on the possibility of requiring periodic reporting for legally marketed 510(k) devices.
6. Potential other solutions – FDA seeks comments on combinations of the options above, or other options not mentioned here.

- Date, Time and Location [1]
- Federal Register Notice
- Agenda [2]
- Registration [3]
- Public Comment [4]

- Workshop Details [5]
- Contact Us [6]

Date, Time and Location

This meeting will be held on **May 17, 2013** beginning at 9 a.m at the following location:

FDA White Oak Campus
10903 New Hampshire Avenue
Bldg. 31, Room 1503 (the Great Room),
Silver Spring, MD, 20993

- FDA Campus Information [7]

This public meeting will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. on May 3, 2013. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after May 13, 2013. If you have never attended a Connect Pro event, test your connection [8]. A quick overview of the Connect Pro program [9] is also available.

Preliminary Agenda (All times are tentative)

Time	Subject
9:00 AM	Introduction
9:15 AM	FDA Presentation
10:00 AM	External Stakeholder Presentations
11:00 AM	Break
11:15 AM	External Stakeholder Presentations, continued
12:15 PM	Lunch
1:15 PM	External Stakeholder Presentations, continued
2:15 PM	Break
2:30 PM	Panel Discussion
3:45 PM	Open Comment Period
4:15 PM	FDA Close-out
4:30 PM	Adjournment

Registration to Attend the Meeting

If you wish to attend this meeting, you must register by close of business on Friday, May 10, 2013.

There is no fee to register for the meeting and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited.

Attendance	● In-Person ❍ Webcast
Title	● Mr. ❍ Mrs. ❍ Ms. ❍ None
First Name *	
Last Name *	M.D.❑ Ph.D.❑
Email*	
	Please enter Email again for verification :
Phone Number*	(No dashes or spaces in phone numbers please)
Company or Organization *	
Request to Present *	If you wish to present during open public comment session, please pick a topic you wish to address. (You can select or unselect multiple topics by holding down your Control key while clicking.)

Risk Management
ce on design control a
l specifications
Risk-based stratification for
Periodic reporting
Other policy proposals

Submit Clear Form

Public Comment

In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the meeting topics. FDA would like to receive these comments by May 10, 2013, so they can be discussed during the meeting, however, comments related to this meeting will be accepted until June 17, 2013.

Regardless of attendance at the meeting, interested persons may submit either written comments regarding this document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.1061, Rockville, MD 20852 or electronic comments to http://www.regulations.gov [10].

If you wish to make an oral presentation during any of the open comment sessions at the meeting you must indicate this at the time of registration. FDA requests that presentations focus on the topics defined in the Federal Register Notice. You should also identify which discussion topic you wish to address in your presentation. In order to keep each open session focused on the discussion topic at hand, each oral presentation should address only one discussion topic. FDA will do its best to accommodate requests to speak. FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by May 10, 2013. If selected for presentation, any presentation materials must be emailed to Michael Ryan, Michael.ryan@fda.hhs.gov [11] no later than May 13, 2013. No commercial or promotional material will be permitted to be presented or distributed at the meeting.

Workshop Details

Food and Beverages will be available for purchase during the breaks.

If you require special accommodations due to a disability, or need additional information regarding registration, please contact Joyce Raines,Office of Communications, Education, and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 66, Silver Spring, MD 20993, 301-796-5709, FAX: 301-847-8142, joyce.raines@fda.hhs.gov [12].

Contact Us

For questions regarding meeting content please contact:

Michael J. Ryan
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave.
Bldg. 66, rm. 1615
Silver Spring, MD 20993-0002
Phone: 301-796-6283,
michael.ryan@fda.hhs.gov [13]

Links:
[1] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#date
[2] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#agenda
[3] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#registration
[4] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#public
[5] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#details
[6] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#contact
[7] http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm
[8] https://collaboration.fda.gov/common/help/en/support/meeting_test.htm
[9] http://www.adobe.com/go/connectpro_overview
[10] http://www.regulations.gov
[11] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/mailto:Michael.ryan@fda.hhs.gov
[12] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/mailto:joyce.raines@fda.hhs.gov
[13] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/mailto:

michael.ryan@fda.hhs.gov