

Dear Medical Device Association:

In the Federal Register of January 27, 2010 (75 FR 4402), FDA published a notice announcing a public meeting on February 18, 2010, and the opening of a public docket to receive comments on key challenges related to the premarket notification (or 510(k)) process for the review of medical devices. Specific questions for comment were listed and interested persons were invited to submit comments by March 5, 2010.

<http://edocket.access.gpo.gov/2010/2010-1620.htm>

At this time, the agency is extending the comment period until March 19, 2010, to continue to receive public comments. Comments submitted to the docket will assist in identifying actions that the Center for Devices and Radiological Health can consider taking to strengthen the 510(k) process.

The Federal Register Notice [Docket No. FDA-2010-N-0054] Notice of extension of comment period can be found at:

<http://www.regulations.gov/search/Regs/contentStreamer?objectId=09000064>

Updated information including a link to the video recording of the meeting can be found at:

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm193>