

CDRH/FDA Public Webinar: FDA Discussion on the Draft 510(k) and Use of Science in Regulatory Decision Making Reports

August 31, 2010 -- 1:00 pm (EST) 10:00 am (PST)

CDRH has published Preliminary Internal Evaluations, including comprehensive assessments on both the 510(k) Premarket Review Process, and the Use of Science in CDRH's Regulatory Decision Making. On Tuesday, August 31, 2010, CDRH will host a live webinar to discuss the details of both reports and respond to any questions and concerns raised by the medical device community. The webinar can be viewed at the link below:

<http://fda.yorkcast.com/webcast/Viewer/?peid=8fed89730ec045e9add6b222f8686a45>

Please note that CDRH has published a notice in the Federal Register requesting public comment on these reports: Docket No. FDA-2010-N-0348, "Center for Devices and Radiological Health 510(k) Working Group Preliminary Report and Recommendations, and Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations; Availability for Comment."

After the 60-day comment period has closed and we have reviewed all public comments, CDRH will announce the recommendations they plan to adopt, along with an appropriate implementation timeline.

Both reports can be found at:

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm220272.htm>