Medical Device Forum: FDA 510(k) Recommendations: Overview of Comments and Next Steps

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Future changes in the 510(k) process as suggested in the US Food and Drug Administration's January 2011 510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision Making. The 510(k) Working Group was charged with evaluating how well the 510(k) program was meeting public health goals and exploring actions the Center for Devices and Radiological Health should take to strengthen it. FDA solicited and received a range of comments on reports from industry, venture capitalists, healthcare professional organizations, third-party payers, patient and consumer...