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ALERTS

Food, Drug & Device Law Alert - FDA Issues List Of Medical Device Guidance Documents Planned For 2013

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Late last year, the FDA's Center for Devices and Radiological Health (CDRH) issued a list of the medical device final guidance and draft guidance documents it intends to issue in 2013. The list appears below:

Final Guidance Topics

- Refuse to Accept (RTA) Policy for 510(k) Submissions
- Acceptance and Filing Review for Premarket Approval Applications
- Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies
- In Vitro Companion Diagnostic Devices
- Design Considerations for Pivotal Clinical Investigations for Medical Devices
- De Novo Classification Process (Evaluation of Automatic Class III Designation)
- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications
- CDRH Appeals Processes
- Medical Device Classification Product Codes
- The Pre-Submission Program and Meetings with FDA Staff
- Mobile Medical Applications
- eCopy
- Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents

Draft Guidance Topics

- Distinguishing and Reporting Medical Device Recalls from Product Enhancements
- Types of Communication During the Review of Medical Device Submissions

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RELATED PRACTICE AREAS

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- FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations
- eCopy
- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions

CDRH actually issued the first two guidance documents on the final list -- dealing with acceptance (or not) of 510(k) notifications and Premarket Approval Applications – and the one on eCopy at the end of 2012. Many of the others on the final list were of course the subject of draft guidance documents issued last year and summaries of several of them can be found at www.btlaw.com by clicking on News & Publications and then Alerts.

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