U.S. FDA
CENTER FOR DEVICES AND RADILOGICAL HEALTH
UPDATE

Jeff Shuren
Director
Center for Devices and Radiological Health
<table>
<thead>
<tr>
<th>Provision</th>
<th>Implementation activities completed</th>
<th>Date completed</th>
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<tbody>
<tr>
<td>Least Burdensome</td>
<td>Issued draft guidance (not mandated); trained staff</td>
<td>15 Dec 2017</td>
</tr>
<tr>
<td>CLIA Waiver</td>
<td>Issued draft guidance</td>
<td>29 Nov 2017</td>
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<tr>
<td>Breakthrough Devices</td>
<td>Issued draft guidance</td>
<td>25 Oct 2017</td>
</tr>
<tr>
<td>Classification Panels</td>
<td>Published FR Notice soliciting public input for panel membership; finalized “Procedures for Meetings of the Medical Devices Advisory Committee” guidance including Cures-related changes</td>
<td>23 Jun 2017 (FR notice) 1 Sep 2017 (guidance)</td>
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<tr>
<td>Cleaning &amp; Validation</td>
<td>Published FR Notice identifying reusable device types for which 510(k)s are required to include certain validation instructions for use and validation data regarding cleaning, disinfection, and sterilization</td>
<td>9 Jun 2017</td>
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<tr>
<td>Central IRB</td>
<td>Published amendment to regulations removing the word “local” where needed to comply with new law</td>
<td>7 Jun 2017</td>
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<tr>
<td>Humanitarian Device Exemptions</td>
<td>Amended regulations changing the HDE population limit from 4,000 to 8,000</td>
<td>7 Jun 2017</td>
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<tr>
<td>Exemptions</td>
<td>Published lists of Class I and Class II devices exempt from requirement to submit a 510(k)</td>
<td>Final Class I list: 13 Apr 2017 Final Class II list: 11 Jul 2017</td>
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<tr>
<td>Software</td>
<td>Detailed on subsequent slides</td>
<td></td>
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# Digital Health Guidance Documents

<table>
<thead>
<tr>
<th>Title</th>
<th>Draft or Final</th>
<th>Date Issued</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple Function Device Products: Policy and Considerations</td>
<td>Draft</td>
<td>TBD</td>
<td>Clarifies FDA oversight of products with software functions both within and outside our jurisdiction</td>
</tr>
<tr>
<td>Software as a Medical Device (SAMD): Clinical Evaluation</td>
<td>Final</td>
<td>8 Dec 2017</td>
<td>Same as IMDRF document of same title issued 22 Jun 2017</td>
</tr>
<tr>
<td>Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act</td>
<td>Draft</td>
<td>8 Dec 2017</td>
<td>FDA’s current thinking regarding the amended definition of “device” in the Federal Food, Drug, and Cosmetic Act and the resulting effect on medical device software guidances</td>
</tr>
<tr>
<td>Clinical and Patient Decision Support Software</td>
<td>Draft</td>
<td>8 Dec 2017</td>
<td>Provides clarity on the scope of FDA’s regulatory oversight of clinical decision support and patient decision support software</td>
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</tbody>
</table>
Digital Health Public Workshop

- Fostering Digital Health Innovation: Developing the Software Precertification Program
- January 30-31, 2018
- Panels
  - Pre-Cert Pilot Participants
  - Health Care Stakeholders (incl. patients, providers)
  - Trade associations
- Breakout Sessions
  - Enablers of Excellence
  - Measuring Results
  - Aggregating & Scoring
FDARA IMPLEMENTATION

- Request for comments on Voluntary Malfunction Summary Reporting Program (26 Dec 2017)
- Accessories guidance (20 Dec 2017): to implement new review timelines and process for accessories
- Pre-Sub guidance (29 Sep 2017): to update timelines related to scheduling meetings and FDA feedback
- Deficiencies guidance (29 Sep 2017): to clarify that a deficiency should include a reference to a regulation, final guidance, or standard
Clinical Trials

- Final Rule: Human Subject Protection; Acceptance of Data from Clinical Investigations for Medical Devices
  - Issued 21 Feb 2018
  - Requires submission of information about how investigations conform with GCPs
  - Requires a statement regarding compliance with regulations for human subject protection, institutional review boards, and IDEs

- Final Guidance: Acceptance of Clinical Data to Support Medical Device Applications and Submissions
  - Issued 21 Feb 2018
  - Q&A format; provides recommendations to help customers ensure that investigations conducted within the US or OUS comply with the new rule and updated regulations

- Final Guidance: FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions
  - Issued 5 Dec 2017
  - Updated FDA’s criteria for assigning the CMS Category to IDE clinical trials, which supports the Medicare coverage process, especially for early feasibility studies; discusses when it may be appropriate to change categories
NEW APPROACHES

• Final Guidance: Deciding When to Submit a 510(k) for a Change to an Existing Device
  – Issued 25 Oct 2017

• Final Guidance: Deciding When to Submit a 510(k) for a Software Change to an Existing Device
  – Issued 25 Oct 2017

• Fostering Medical Innovation: Case for Quality Voluntary Medical Device Manufacturing & Product Quality Pilot
  – Announced in Federal Register 28 Dec 2017
  – Goals: improve patient safety and outcomes, reduce regulatory burden on demonstrating quality assurance, assure safety and effectiveness
2018-2020 Strategic Priorities

• Employee Engagement, Opportunity, and Success

• Simplicity

• Collaborative Communities

THANK YOU