Developing a Mobile Medical App?
How to determine if it is a medical device and get it cleared by the US FDA

In this presentation:
• App stats: Explosive growth
• Examples already cleared by the US FDA
• Is your app a medical device?
• FDA guidance on mobile medical devices
• Medical Device Data Systems (MDDS)
• The FDA 510(k) process
• Software validation requirements
• Emerging issues and concerns

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App Stats

• There are roughly 19,000 apps classified as “Health and Fitness” or “Medical” in the iTunes store
• “Health and Fitness” and “Medical” apps account for 4% of all apps in iTunes
• Apple receives about 650 new non-game app submissions daily
• Apple’s approval times for new app submissions usually take four days
Examples of Mobile Devices Cleared by the FDA

MobiUS by MobiSante
Portable ultrasound
K102153
Cleared by FDA: Jan 2011

Mobile MIM by MIM Software
Radiological image processing
K103785
Cleared by FDA: Feb 2011
Examples of Mobile Devices Cleared by the FDA

VueMe by MIM Software
Remote imaging tool
K103576
Cleared by FDA: Feb 2011

AirStrip RPM by Airstrip Technologies
Remote patient ECG monitoring
K110503
Cleared by FDA: March 2011
Case Study: Mobile MIM and the FDA

Mobile MIM, manufactured by MIM Software to provide radiological image processing via iPhone, illustrates the challenges many app makers can face obtaining FDA clearance or approval.

- In 2008, Mobile MIM was among the first apps made available in Apple’s new AppStore.
- Later that same year, the FDA notified MIM Software that the Mobile MIM app may require regulatory review, and the firm removed the product from the AppStore.
- The FDA initially planned to review Mobile MIM via premarket approval (PMA), but eventually allowed a 510(k) submission for the app.
- MIM Software finally received 510(k) clearance for Mobile MIM in February 2011.

Source: http://mobihealthnews.com/11066/mim-vueme-app-helps-patients-share-dicom-images/
FDA Guidance on Mobile Medical Devices

Highly anticipated FDA guidance released in July 2011 indicates which mobile medical apps fall under medical device regulatory requirements, and which do not. Although not all types of mobile medical apps are covered by the guidance, the FDA’s proposed rules show that the agency will not be taking a one-size-fits-all approach to these products.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm
Your App is Likely a Device if it:

<table>
<thead>
<tr>
<th>Amplifies</th>
<th>Cures</th>
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<td>Analyzes</td>
<td>Detects</td>
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<td>Attaches</td>
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<td>Alarms</td>
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<td>Calculates</td>
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<td>Controls</td>
<td>Trends</td>
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<td>Converts</td>
<td>Treats</td>
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• *But*, manufacturers should take into account several criteria, such as their apps’ intended uses and how they interact with other devices, when determining whether their products qualify as medical devices.
FDA Criteria for Determining if an App is a Medical Device

- Is the app a component of a medical device?
- Is the app an accessory to a medical device?
- Is the app intended for use in the diagnosis, treatment, mitigation or prevention of a disease?

If the answer to any one of these questions is yes, the FDA considers your app a medical device.
FDA Criteria for Mobile Medical Apps

Specific criteria for apps as medical devices:

1. Mobile medical apps that serve as extensions of regulated medical devices and control those devices or display, store, analyze or transmit patient-specific medical device data
2. Mobile medical apps that transform mobile platforms into regulated medical devices by using attachments or similar medical device functions
3. Mobile medical apps that allow users to input patient-specific data and output patient-specific results or diagnoses using formulae or processing algorithms
The FDA’s guidance lists the following categories of mobile medical apps that qualify as medical devices:

<table>
<thead>
<tr>
<th>Category</th>
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<tr>
<td>Apps for displaying, storing or transmitting patient-specific medical device data in its original format</td>
</tr>
<tr>
<td>Apps that control intended use, functions or energy sources of medical devices to which they connect</td>
</tr>
<tr>
<td>Apps that transform mobile platforms into medical devices</td>
</tr>
<tr>
<td>Apps that analyze medical device data to create alarms, recommendations or new information</td>
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</table>
Mobile Medical App Firms NOT Regulated by the FDA

Firms that distribute mobile medical apps—iTunes and Blackberry App World, for example—but do not actually develop and/or manufacture those products are not considered mobile medical app manufacturers.
The US Regulatory Approach to Mobile Medical Apps

FDA Guidance on Mobile Medical Apps Does NOT Address:

| Wireless safety and security considerations |
| Application of quality systems to software |
| Classification and submission requirements for clinical decision support software |
| Mobile medical apps that process data from multiple medical devices |

The FDA plans to issue separate guidance documents in the near future to address these topics.
Medical Device Data Systems

The FDA’s Medical Device Data Systems (MDDS) category of devices covers products used to transfer, store, convert or display medical device data. Devices falling under the MDDS are designated as Class I, and are exempt from FDA premarket notification requirements in the US. Some mobile medical apps also fall under this category.
## Does Your App Qualify as MDDS?

*Devices that provide one or more of the following functions without controlling or altering how connected devices operate qualify as MDDS products:*

<table>
<thead>
<tr>
<th>• Electronic transfer of medical device data</th>
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<tr>
<td>• Electronic storage of medical device data</td>
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<tr>
<td>• Electronic display of medical device data</td>
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</table>

*The scope of MDDS can include mobile medical apps as well as software, hardware, modems, interfaces and communication protocols.*
Examples of MDDS Devices

- Customized software not written by the original manufacturer that connects to a medical device in order to obtain data
- Modified software or hardware components created for MDDS functionality within a larger IT infrastructure
Devices that DO NOT Qualify as Medical Devices

*General-purpose technologies used by health care providers but not modified from their out-of-the-box configurations typically do not qualify as MDDS products.*

<table>
<thead>
<tr>
<th>Data Transfer</th>
<th>Data Storage</th>
<th>Data Conversion</th>
<th>Data Display</th>
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<tbody>
<tr>
<td>• Network routers</td>
<td>• Network attached storage (NAS)</td>
<td>• Virtualization systems</td>
<td>• Computer monitors</td>
</tr>
<tr>
<td>• Network hubs</td>
<td>• Storage Area Networks</td>
<td>• PDF software</td>
<td>• Big-screed display units</td>
</tr>
<tr>
<td>• Wireless access points</td>
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More Examples of Technologies **Outside the Scope of MDDS**

- Networks that monitor medical devices for malfunctions
- Standard IT software not sold by the manufacturer as MDDS but used to read serial numbers, bar codes and other data from medical devices
- Off-the-shelf “network sniffing” software for monitoring network performance and that does not connect directly to a medical device
MDDS Compliance

All MDDS manufacturers must meet FDA Class I medical device requirements

Hints for MDDS Registration and Listing

1. Use Product Code OUG for registration and listing
2. Leave Premarket Submission Number entry blank
3. Under “Proprietary Name,” enter a generic system name such as “X Hospital MDGS”
The US FDA Regulatory Process for Medical Devices

Mobile medical apps fall under the same regulatory requirements as other medical devices. Whether an app is classified as Class I, II or III depends on the level of risk it poses to users, as well as whether Substantial Equivalence exists.
The US Regulatory Approach to Mobile Medical Apps

How to Determine FDA Classification and Regulatory Pathway

Go to [www.fda.gov/medicaldevices](http://www.fda.gov/medicaldevices) and search for “product classification” using the site’s search box. This will lead you to the Product Classification Database.
The FDA Product Classification Database

Use the Product Classification Database to identify Predicate Devices similar to your app.

Use the most basic description of your device to conduct your search. Use the “Search” button, not the “Go to simple search” option, for better search results.
Review Search Results for Products Similar to Yours

Select products from the list of search results that best fit with your device’s description to see further details and determine which product would best serve as your predicate device.
The US Regulatory Approach to Mobile Medical Apps

Determining Your Path to Compliance

Regulation numbers will provide detailed descriptions of each device.
Evaluate Product Description (Intended Use) to Identify Your Predicate Device
The US Regulatory Approach to Mobile Medical Apps

## FDA Clearance or Approval

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<tr>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
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<tr>
<td>No FDA review needed.</td>
<td>FDA clearance required via 510(k) Premarket Notification. Predicate; “Me too” devices.</td>
<td>FDA approval required via Premarket Approval (PMA) process. Novel; no predicates.</td>
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Mobile medical apps can fall into any of these three classes.
FDA Clearance/Approval Timelines

<table>
<thead>
<tr>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
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<tr>
<td>Process typically takes 5 to 7 working days. Self-register your device and pay FDA fee. Some Class 1 products do require a 510(k) submission.</td>
<td>Most 510(k) applications reviewed within 90 days, but the entire process can take between 4 and 10 months. Average timeline is 132 days from submission to FDA clearance...for all products.</td>
<td>Process takes 36 months or more depending on clinical trial requirements and FDA requests for additional information. Premarket approval reviews take 180 days.</td>
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</table>
Steps in FDA’s Compliance Process

Below are broad steps manufacturers of Class I, II and III medical devices must typically go through to obtain clearance or approval from the US FDA.

1. Determine device classification.
2. Prepare and file 510(k) submission, if required.
4. Appoint US Agent, if outside US.
5. Register with FDA. Pay fee.
Quality System Requirements

Class I and all Class II and III medical devices, including mobile medical apps, must implement quality management systems compliant with FDA Quality System Regulations (QSR) found in 21 CFR Part 820.

- The FDA does not recognize ISO 13485 or ISO 9001 certification—only QSR (aka current Good Manufacturing Practice) compliance is accepted in the US.
- The FDA does not certify quality systems. Instead, the agency conducts random inspections to determine QSR compliance.
- Even if a manufacturer outsources production of a device or app, that firm must still comply with quality system requirements.
Implementation Timelines for Quality Systems

- For manufacturers with less than 50 employees and a single facility, implementation typically takes **3 to 6 months** to complete.
- For manufacturers with more than 50 employees and more than one facility, implementations can take **5 to 9 months** to complete.
Steps to FDA Quality System Compliance

*Phase I: Analysis and Planning*

- Conduct gap analysis of existing quality assurance processes to determine strengths and weaknesses in terms of FDA QSR compliance
- Conduct project awareness training to ensure buy-in from all employees in your organization
Steps to FDA Quality System Compliance

Phases II and III: Documentation Development and Implementation

• Set quality policy and quality objectives
• Write quality system procedures (QSPs), quality manual and associated forms covering document control, design and development, corrective and preventative actions and other issues
• Begin using QSPs
• Develop records to demonstrate your firm is following your QSPs
Steps to FDA Quality System Compliance

**Phases IV and V: Internal Auditing and Monitoring**

- Following full implementation and record creation, conduct internal audits to assess readiness of your new quality system.
- Gather audit findings, determine if there are any deficiencies or weaknesses in your quality system process, and address those issues to ensure full FDA QSR compliance.
Mobile Medical Apps and Software Validation

The Quality System Regulation’s validation requirements apply to software serving as a component of a medical device; software that functions as a stand-alone medical device; and software used in the production of a medical device or the implementation of a manufacturer’s quality system.
Scope of Software Validation Requirements

These types of software are subject to QSR validation regulations:

- Software that automates any part of a device production or quality management system process
- Computer systems that create, modify or maintain electronic records and signatures
- Production or quality system software bought off the shelf for specific intended uses must also go through validation
Steps in the Software Validation Process

Although the QSR does not prescribe specific software validation rules, the FDA does provide general guidelines on how to meet these requirements.

<table>
<thead>
<tr>
<th>1. Quality Planning</th>
<th>5. Testing by Software Developer</th>
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<tr>
<td>2. System Requirements</td>
<td>6. User Site Testing</td>
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<tr>
<td>3. Design</td>
<td>7. Maintenance and Software Changes</td>
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</tbody>
</table>
## Software Validation: Quality Planning

1. Identify necessary tasks and procedures, resources and management review requirements such as formal design reviews

2. Identify software lifecycle model, risk and configuration management plans, and software quality assurance plan

3. Assign methods and procedures as well as roles, resources and responsibilities

4. Identify problem reporting and resolution procedures
# Software Validation: Design

1. Describe your software’s functions and how it does them

2. Include human factors in your design to address user error issues

3. Design should include software requirement specifications, risk analysis, coding guidelines, systems documentation and required hardware

4. Conduct a formal design review at the end of this phase in order to verify that your design is correct and testable
### Software Validation: System Requirements

1. Identify, analyze and document data pertaining to your device and its intended use

2. Allocation of system functions to software, operating conditions, potential hazards and user characteristics are some factors to be considered

3. Develop written definition of software functions

4. Establish mechanism to address any ambiguous, inconsistent or conflicting requirements

5. Conduct traceability analysis to trace software requirements to system requirements and risk analysis results
Software Validation: Construction or Coding

1. Develop software either by coding or building software components from other sources
2. Conduct source code traceability analysis to verify that all code links to established specifications and test procedures
3. Evaluate source coding and source code documentation
4. Analyze source code interface
5. Generate test procedures and test cases
# Software Validation: Testing by Software Developer

1. Create test plans and cases to identify schedules, resources and methodologies

2. Predefine expected test outcomes

3. Ensure testing is independent from coding

4. Ensure that test documentation permits reuse and confirmation of results
Software Validation: User Site Testing

1. Testing should occur at user’s facility with actual hardware and software that will make up the product’s final configuration

2. Testing should follow pre-defined plans, and all procedures, input data and results should be documented

3. Users’ ability to understand and interface with the product should be evaluated

4. Records of proper system function as well as failures occurring during the user testing process should be kept

Typical User Site Testing tasks include acceptance test execution, test result evaluation, error evaluation and final test reports.
Software Validation: Maintenance and Software Changes

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<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>Corrective maintenance to correct software errors or faults</td>
</tr>
<tr>
<td>2</td>
<td>Perfective maintenance to improve software performance or functionality</td>
</tr>
<tr>
<td>3</td>
<td>Adaptive maintenance to make software useable in a changed environment</td>
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</table>
Software Validation: Validating Automated Process Equipment and Quality System Software

1. Required validation evidence
2. Defined user requirements
3. Validation of off-the-shelf software and equipment
The mobile medical app market has only begun to take off.

Most apps already registered with the FDA have gone through the 510(k) review process—but manufacturers should not assume that premarket notification will be the *de facto* path to market for these products.

2011 FDA guidance on mobile medical app regulation indicates that existing US medical device regulatory structures will be applied to medical apps as well.

App manufacturers new to the FDA regulatory process should familiarize themselves with issues such as 510(k) clearance, Medical Device Data Systems and FDA Good Manufacturing Practices.
Emerging Issues Regarding Mobile Medical Apps

- Where does liability for data security lie?
- How should mobile medical app manufacturers address data encryption and HIPAA issues?
- What (if any) regulatory responsibility do component suppliers to medical app manufacturers bear?
- Will the FDA’s existing regulatory framework for conventional medical devices work for oversight of mobile medical apps?
The US Regulatory Approach to Mobile Medical Apps

Resources:

FDA guidance document on mobile medical apps:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm

List of major FDA regulations and guidance documents:
http://www.emergogroup.com/resources/regulations-united-states

Our services for mobile medical app/telehealth compliance:
http://www.emergogroup.com/services/worldwide/mobile-health-app-consulting

Emergo Group iPhone® app
Download it free in the iTunes® app store.