Morgan Lewis

BRINGING YOUR DIGITAL HEALTH PRODUCT TO MARKET

Understanding the FDA and FCC hurdles that may impact product development

TECHNOLOGY MAY-RATHON

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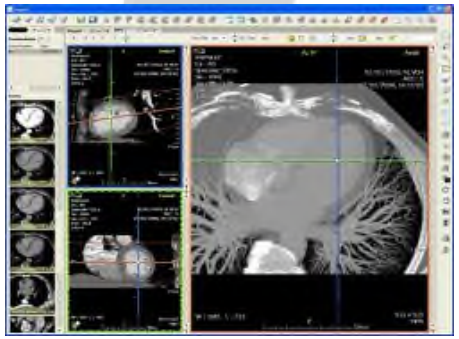
What is Digital Health?

- Wide range of medical and health/fitness technologies:
  - Health information technology
  - Clinical decision support software
  - Telehealth systems and devices
  - Fitness apps and wearables
  - Electronic health records
  - Mobile medical apps
  - Remote monitoring sensors/systems
  - Machine learning/data analytics
  - Medical imaging systems



FOOD & DRUG ADMINISTRATION REGULATION

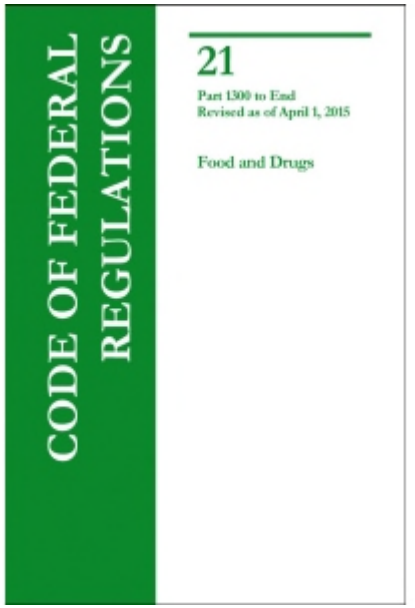
Current FDA Regulatory Climate

- Factors creating uncertainty regarding the current regulatory status of digital health products:

  - Recent actions by FDA to deregulate low-risk digital health and mobile medical app products
  - FDA's use of enforcement discretion
  - Outstanding gaps in FDA guidance
  - FTC enforcement and regulation
  - Congressional legislation

Assessing the Impact of FDA Regulation

- Is my product regulated by FDA?
  - Is it a "medical device" or an "accessory"?
  - If it's a medical device, is it subject to enforcement discretion?
    - Is it a "general wellness" device?
    - Is it a health IT product?
    - Is it a mobile medical app?



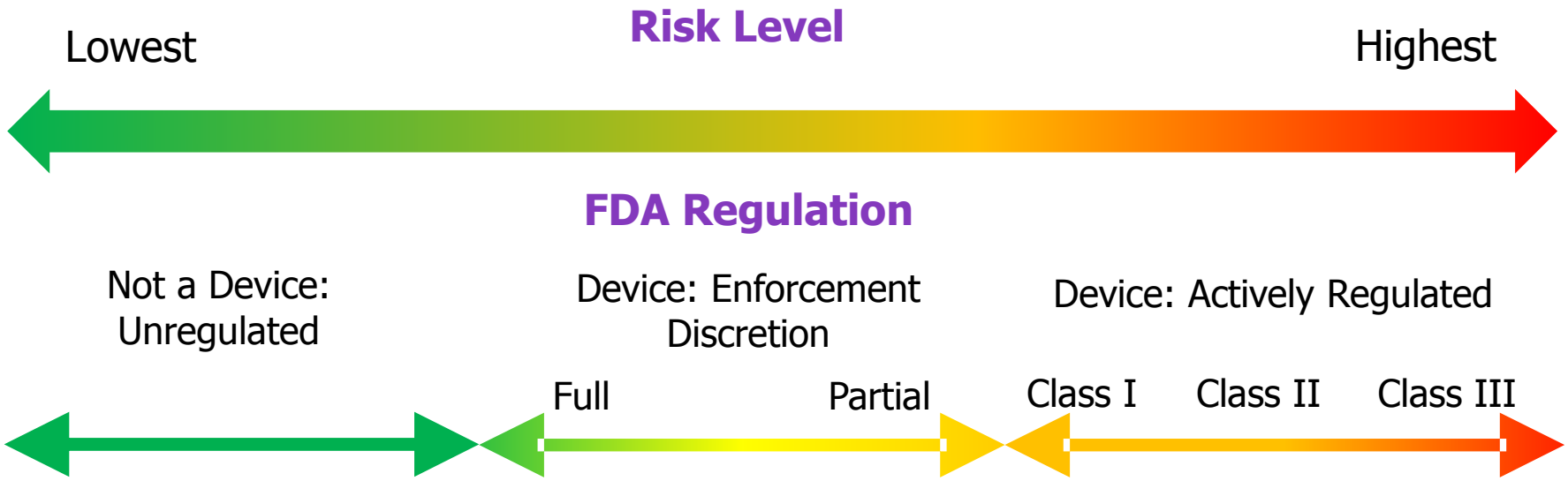
- If it's an FDA-regulated device, what premarket and postmarket requirements apply?

Is My Product a Medical Device?

- Under the FFDCA, a device includes:
  - Any thing (any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar related article, including any component, part, or accessory)
  - Intended to be used for a health/medical purpose (intended for use in the diagnosis of disease or other conditions; or in the cure, treatment, or prevention of disease; or to affect the structure or function of the body)
  - That is not a drug (i.e., does not achieve its principal purposes by chemical action in or on the body of man or by being metabolized)

Enforcement Discretion

- FDA may choose not to actively regulate low-risk devices under a policy of *enforcement discretion*
- FDA may apply enforcement discretion to exempt certain devices from *all* or *some* of the FDA regulatory requirements (e.g., enforcement discretion for 510(k) requirement only)



General Wellness: Policy for Low-Risk Devices

- Once finalized, the draft guidance would exempt from FDA oversight products that:
  - Are intended <u>only</u> for general wellness uses
    1. An intended use that relates to maintaining or encouraging a general state of health or a healthy activity, <u>or</u>
    2. An intended-use claim that associates the role of a healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases
  - Present a very low risk to users' safety

FDASIA Health IT Report

- Mandated by Congress under the Food and Drug Administration Safety and Innovation Act (FDASIA)
- Proposes a limited approach that "relies on ONC-coordinated activities and private sector capabilities"
- Focused primarily on health IT in healthcare settings or used by or under the supervision of a healthcare provider
- Does not address health IT marketed for use by consumers/patients

FDASIA Health IT Report

- Identifies three categories of health IT based on function:
  - Administrative health IT functions
    - E.g., billing, claims processing, practice and inventory management, general purpose communications, and scheduling
    - Not subject to FDA oversight
  - Health management health IT functions
    - E.g., health information and data management, data capture and encounter documentation, electronic access to clinical results, medication management, electronic communication and coordination, provider order entry, knowledge management, patient identification and management, and "most clinical decision support" technologies
    - Not subject to FDA oversight
  - Medical device health IT functions
    - E.g., computer-aided detection and diagnosis, remote display of alarms from bedside monitors, radiation treatment planning, robotic surgical planning and controls, and electrocardiography analytical software
    - Subject to FDA oversight

Mobile Medical Applications Guidance

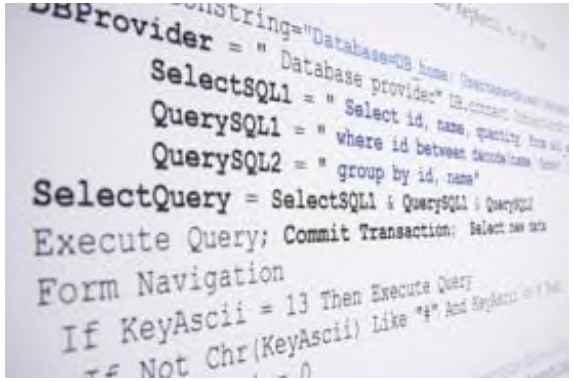



- Describes "FDA's intentions to focus its oversight on a subset of mobile apps" that "pose[] the same or similar risks to the public health as currently regulated devices if they fail to function as intended."
- Identifies three categories of apps:
  - Apps that FDA intends to regulate as medical devices
  - Apps that may meet the statutory definition of a "device" but for which FDA intends to exercise enforcement discretion
  - Apps that do not meet the statutory definition of a "device" and that FDA will not regulate

Digital Health:
Mobile Medical Applications

- Health and wellness apps (not actively regulated – enforcement discretion)
  - Apps that help patients self-manage their diseases or conditions without providing specific treatment or treatment suggestions
  - Apps that provide patients with simple tools to organize and track their health information
  - Apps that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health, or wellness

Who Is Responsible for FDA Compliance?



- Generally, FDA puts the responsibility for FDA compliance on the device "manufacturer"
- A "manufacturer" includes more than a physical manufacturer of a device
- Activities that result in manufacturer responsibilities:
  - Manufacture, preparation, propagation, compounding, assembly, or processing of a medical device
  - Repackaging to change the container, wrapper, or labeling
  - Initial importation of a device
  - Initiation of device specifications
- FDA regulates the manufacturer of the final, *finished device* – not component manufacturers

FDA Regulatory Obligations for Devices

Premarket Obligations

- Design controls (21 C.F.R. § 820.30)
- Clinical testing compliance (if applicable) (21 C.F.R. Part 812)
- Premarket submission (if applicable) (21 C.F.R. Part 807, Subpart E and 21 C.F.R. Part 814)

Postmarket Obligations

- Establishment registration and device listing (21 C.F.R. Part 807, Subparts A-D)
- Good manufacturing practices (GMPs)/Quality System Regulation (QSR) (21 C.F.R. Part 820)
- Labeling (21 C.F.R. Part 801)
- Medical device reporting (21 C.F.R. Part 803)
- Reporting of corrections and removals (21 C.F.R. Part 806)

Premarket Submissions

- Class I: No premarket submission required (limited exceptions)
- Class II: Premarket Notification (510(k))
  - Must demonstrate that the device is substantially equivalent to a pre-1976 device or a device previously cleared by a 510(k) (*i.e.*, a predicate device)
  - Required for initial marketing or for certain device modifications
- Class III:
  - Premarket Approval (PMA)
    - Requires proof of device safety and effectiveness – generally one or more prospective, adequately controlled, clinical trials
    - Supplement approval required for changes that affect safety and effectiveness
  - De Novo Petition for Down-classification
    - Only for novel, unclassified devices that are Class III by default – not for devices classified as Class III by FDA regulation
    - Requires demonstration that the device is low or moderate risk, such that it may be reclassified as Class I or II

Recent and Anticipated Developments

- Outstanding FDA Guidance
  - Clinical decision support
  - Machine learning
- FTC Regulation and Enforcement
  - FTC enforcement thus far is generally consistent with FDA's policies
  - New web-based tool for developers of health-related apps
- New Pending Legislation

FEDERAL COMMUNICATIONS COMMISSION REGULATION

FCC Basics

- Within the FCC, the Office of Engineering and Technology (OET) manages radiofrequency (RF) spectrum and ensures that RF equipment sold and marketed in the United States does not cause interference with other radio services or products.
- Before selling or marketing a "radiofrequency device" you must obtain appropriate FCC equipment authorization.
- What is a "radiofrequency device"? Pursuant to FCC rules, it is "any device which in its operation is capable of emitting radiofrequency energy by radiation, conduction, or other means."

FCC Basics

- The FCC rule part applicable to the device dictates the type of approval
- **DoC**:
  - Manufacturer must undertake testing at an approved laboratory and make a declaration that the device conforms to the appropriate limits for RF emissions
  - Test data not released to the public, but must be disgorged if the FCC inquires
  - DoC devices affixed with stylized FCC marking and warning concerning RF interference
- **Certification**:
  - Involves lengthy testing and a grant of authority from a Telecommunications Certification Body (TCB) with delegated authority from the FCC
  - Test reports and extensive documentation (schematics, pictures, operation manuals) maintained and publicly accessible in the OET EAS
  - Certificated devices identified with a unique FCC ID affixed on a permanent label
- **Verification**:
  - Manufacturer verifies that the equipment meets the performance metrics if appropriately installed
  - End user resumes responsibility for the operation of the device and rule compliance

FCC Basics

Sample Devices – Declaration of Conformity:

- Computers and peripherals
- Consumer electronics
- Appliances
- Electronic toys
- Power supplies

- Residential medical devices w/o wireless transmitter features

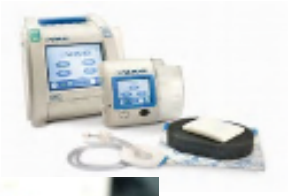
Common Traits:

- Spurious, unintentional radiators (i.e., any RF emissions are an unintended consequence of oscillators or other internal electronics components that cannot be completely shielded).
- Generally no detectable RF energy beyond a few feet
- Can create interference at short distances if improperly installed or modified or if defective

FCC Basics

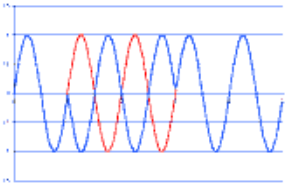
Sample Devices – Certification:

- Wi-Fi access points
- Mobile phones
- Bluetooth devices
- Wireless microphones
- IOT and SCADA transmitters



- Cellular and wireless-enabled medical devices
- RFID readers
- UWB devices

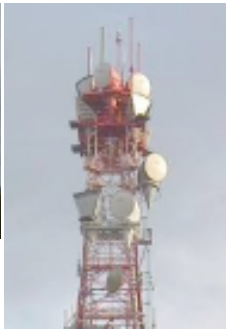
Common Traits:



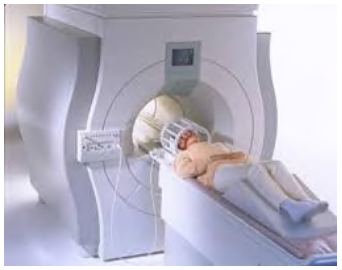
- Active transmitters (i.e., they radiate an intentional, modulated emission or pulse).
- Mass produced (potential for large-scale interference if devices do not satisfy the rules or undergo unauthorized aftermarket modifications)
- Moderate power levels (human safety a consideration, but concerns involve long-term exposure, not imminent harm)

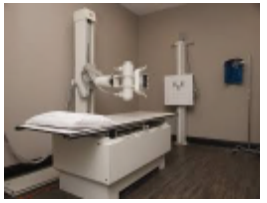
FCC Basics

Sample Devices – Verification:



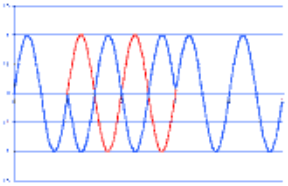
- DTV and radio transmitters
- Satellite ground stations
- Point-to-Point microwave





- MRI machines
- Digital X-rays
- Medical pod

Common Traits:



- Active transmitters (i.e., they radiate an intentional, modulated emission or pulse).
- Custom engineered (not equipment you buy off the shelf; deployment involves months or years of planning; path-loss studies, site surveys, etc.)
- High output (serious public health issues and imminent harm from short-term exposure; immediate area around sites generally secured)
- Licensed end users (end users obtain FCC licenses and assume the ultimate responsibility for the safe installation and operation of the device)

DoC Devices

Before bringing a device authorized pursuant to a DoC to market the manufacturer or importer must:

- Test to confirm spurious emissions from the device fall within Part 15 limits for unintentional radiators.
- Appropriately label the device.

DoC Devices

DoC Testing:

- Two classes of DoC device
  - Class A – Intended for operation in residential settings
  - Class B – Intended for operation in industrial or commercial settings
- Test measurements taken for Class A device at 3 meters of distance and for Class B at 10 meters in a shielded anechoic chamber.

- Limits must not exceed those specified in Section 15.109 of FCC Rules

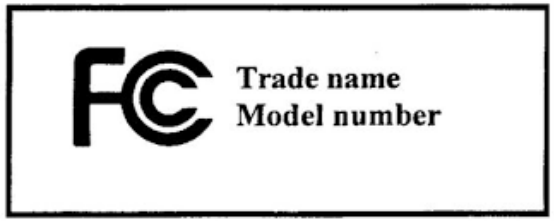
DoC Devices

DoC Test Laboratories:

- DoC testing previously permitted at any laboratory accredited pursuant to an informal FCC process.
- **Effective July 12, 2016, reports will only be accepted from ISO/IEC 17025 accredited test laboratories.**
- This transition has disproportionately impacted testing at Asian laboratories historically involved in DoC testing that have not yet sought ISO/IEC accreditation

DoC Labeling:

- Label must include stylized FCC marking, trade name, and model number



- Permanently affixed (e.g., embossed or etched)
- Legible font (preferably sans-sarif; generally no smaller than 4 points)

Certificated Devices

Certification Testing:

- Testing, development of complementary materials, and grant of authority undertaken by an FCC-approved TCB
- Time-consuming process (2-3 months)
- Generally involves the development of the following materials:
  - Narrative description of how the device operates
  - Block diagram showing the frequency of all oscillators in the device
  - Schematic diagram
  - Test report of measurements showing compliance with the pertinent FCC technical requirements, including the test procedure and sample calculations
  - Photographs clearly showing the exterior appearance of the device under test, the construction, the component placement on the chassis, and the chassis assembly
  - Description of any peripherals or accessories tested with the device
  - Drawing or photograph showing the test setup for each of the required types of tests applicable to the device for which certification is requested
- Most of the above materials are available for public inspection through OET's equipment database; counsel can assist in keeping certain materials (e.g., schematics) confidential

Certificated Devices

Certification Labeling:

- Label must include an FCC ID assigned by the TCB (consists of two elements: a grantee code and an equipment product code)
- Again, must be permanently affixed in a legible font of reasonable size

Additional Language:

- Depending on RF band and rule part, the label may include additional language. For example, WiFi-enabled devices operating in the 2.4 GHz Industrial, Scientific & Medical band must provide the following warning:
  - *"This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation."*
- If the device is too small to include such language, it can be moved to a user manual

Hybrid Devices

- Under "modular transmitter" rules, OEMs can insert a precertificated "plug and play" transmitter in a device.
- Relatively recent development, but increasingly common in medical devices that need to be networked.
- Requires the OEM to place the FCC ID of the embedded modular transmitter on the label of the end product. OEM then tests and prepares a DoC for the device's other components. As a result, the label generally also includes the stylized FCC marking.
- FCC rules prohibit modifications to the modular transmitter that would increase output power, antenna gain, or emission bandwidth.

Preauthorization Testing

- Intentional radiators cannot be tested outside of a tightly controlled laboratory setting without an FCC experimental license.
- Market trials involving prototype devices need a license.
- Short-term special temporary authority can be obtained under exigent circumstances for up to 6 months.
- Longer-term experimental licenses can be obtained for up to 2 years without any special showing (5 years if you have reasonable justification).
- Basic information on the RF characteristics of a device needed to secure experimental license.
  - Transmitter output
  - Antenna gain
  - Geographic area of testing/trials/experiments
- Specifics about the underlying nature of the testing can be kept confidential.

FCC Trends – Internet-of-Things

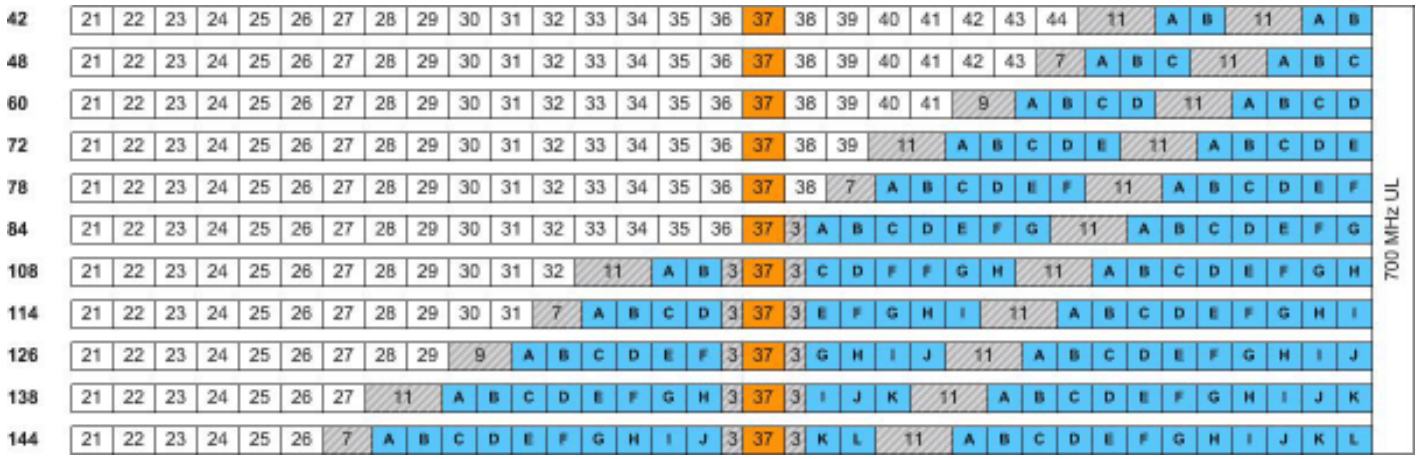
- Certifications for Internet-of-Things (IoT) enabled medical devices increasing exponentially.
- Devices use cellular or unlicensed spectrum to communicate patient status to medical professionals.
- Increasing cooperation between cellular service providers and medical device manufacturers.
- Data transmitted over cellular networks is generally low bit rate, and the carriers can bury it in network overhead.

FCC Trends – Ultra Wideband

- Certifications and waivers for Ultra Wideband (UWB) imaging devices increasing
- Not a traditional communications application; UWB devices emit low-power electromagnetic pulses over a wide swath of frequencies (3-10 GHz) to image the body
- FCC rules on UWB operations restrictive to protect higher priority incumbent uses that fall within the frequency range (satellite communications, terrestrial microwave, broadcast auxiliary services, space exploration, etc.)
- Opposition has arisen to waivers that do not adequately address incumbent interference concerns

FCC Trends – Spectrum Repurposing

- Demand for new services (largely wireless broadband) has the FCC constantly looking at how to do more with less spectrum
- FCC is abandoning efforts to clear frequencies and is focused on shared use
- Medical community is not immune from the impact
- Among other examples, the wireless medical telemetry band at 608-614 MHz (i.e., TV channel 37) post-600 MHz auction will be shared with low-power unlicensed devices and surrounded by noisy licensed broadband transmitters



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