Regulatory Classifications Primer

FDA Definitions

Mobile Platform
For purposes of this guidance, "mobile platforms" are defined as commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature. Examples of these mobile platforms include mobile computers such as smart phones, tablet computers, or other portable computers.

Mobile Application (Mobile App)
For purposes of this guidance, a mobile application or "mobile app" is defined as a software application that can be executed (run) on a mobile platform (i.e., a handheld commercial off-the- shelf computing platform, with or without wireless connectivity), or a web-based software application that is tailored to a mobile platform but is executed on a server.

Mobile Medical Application (Mobile Medical App)
For purposes of this guidance, a "mobile medical app" is a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)4; and either is intended:

- to be used as an accessory to a regulated medical device; or
- to transform a mobile platform into a regulated medical device.

FDA Classifications

Medical Device Data Systems (MDDSs)

- Mobile solutions that display, store, or transfer medical device **data in its original format** without controlling or altering the functions or parameters of any connected medical device constitute a **Medical Device Data System (MDDS) (21 CFR 880.6310)** and are subject to class I requirements (general controls).

Class I (Low Risk)

- Class I are the lowest risk devices with the fewest requirements and generally no premarket submission.
- Class I general controls include these basics: adequate design controls, registration, device listing, adverse event reporting, and corrections and removals.

Class II (Medium Risk)

- Class II devices: General Controls (as described for Class I), Special Controls, and (for most Class II devices) **Premarket Notification.**
- Devices and solutions that provide **medical advice or coaching** are typically classified as Class II

Class III (High Risk)

- Class III devices: General Controls (as described for Class I), and **Premarket Approval (21 CFR Part 814**).
- Implantable monitoring devices are typically classified as Class III