

Mobile Medical Apps and the FDA

Medical Device Regulation 101

- ▶ FDCA (1938) did not regulate medical devices until the MDA of 1976
 - ▶ Contact lenses, e.g., had been regulated as drugs
- ▶ Definition of medical device: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is-
 - ▶ (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
 - ▶ (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
 - ▶ (3) intended to affect the structure or any function of the body of man or other animals, **and**
 - ▶ which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Medical Device Regulation 101

- ▶ Three device classes by increasing risk
 - ▶ Class I—"general controls" only
 - ▶ Class II—requires 510(k) clearance (substantially equivalent to predicate)
 - ▶ Class III—requires PMA (safe and effective)
 - ▶ Clinical trials, investigational device exemptions, and more!
- ▶ Automatic Class III for new device with no predicate
- ▶ Process governed by statutes, regulations, and a sea of guidance documents
 - ▶ Guidance documents: Living on borrowed time?

Software and Medical Devices

- ▶ Internal, medical device-operating software
- ▶ Software related to data collected/stored by the medical device
- ▶ Just plain old software that happens to analyze healthcare data

When does software = a medical device regulated by the FDA?

