

UC DAVIS OFFICE OF RESEARCH

Mobile Medical Applications

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There's an app for that!

- More and more decision support goes to the handheld
- eHealth/Telemedicine – new paradigms, new problems
- Increase convergence between consumer electronics and medical devices



FDA Draft Guidance ~ Mobile Medical Applications

The FDA proposes that the guidance is applicable to mobile medical applications or “mobile medical apps”, defined as:

- “a software application that can be executed (run) on a mobile platform, or a web-based software application that is tailored to a mobile platform but is executed on a server”; **and**
- has an intended use within the scope of the concept of medical “device” as regulated by the FDA; **and**
- transform a mobile platform into a regulated medical device; **or**
- are used as an accessory to a regulated device.

Examples of Mobile Medical Applications

Apps that are extensions of regulated medical devices:

- Allow the user to view medical images on a mobile platform and perform analysis or process for diagnosis;
- Apps that analyze, assess, or interpret electrocardiogram data;
- Apps that connect to a home use diagnostic medical device such as blood pressure meter, body composition analyzer, or blood glucose meter to collect historical data or to receive, transmit, store, analyze, and display measurements from connected devices.

Examples of Mobile Medical Applications (cont.)

Apps that transform or make the mobile platform into a regulated device:

- Apps that attach EKG/EGG leads to a mobile platform to collect/analyze/monitor EKG/EGG signals;
- Apps that generate sine signals from 125Hz to 8kHz (8 steps) to check user's hearing;
- Apps that act as a blood glucose meter by using an attachment to a mobile platform.

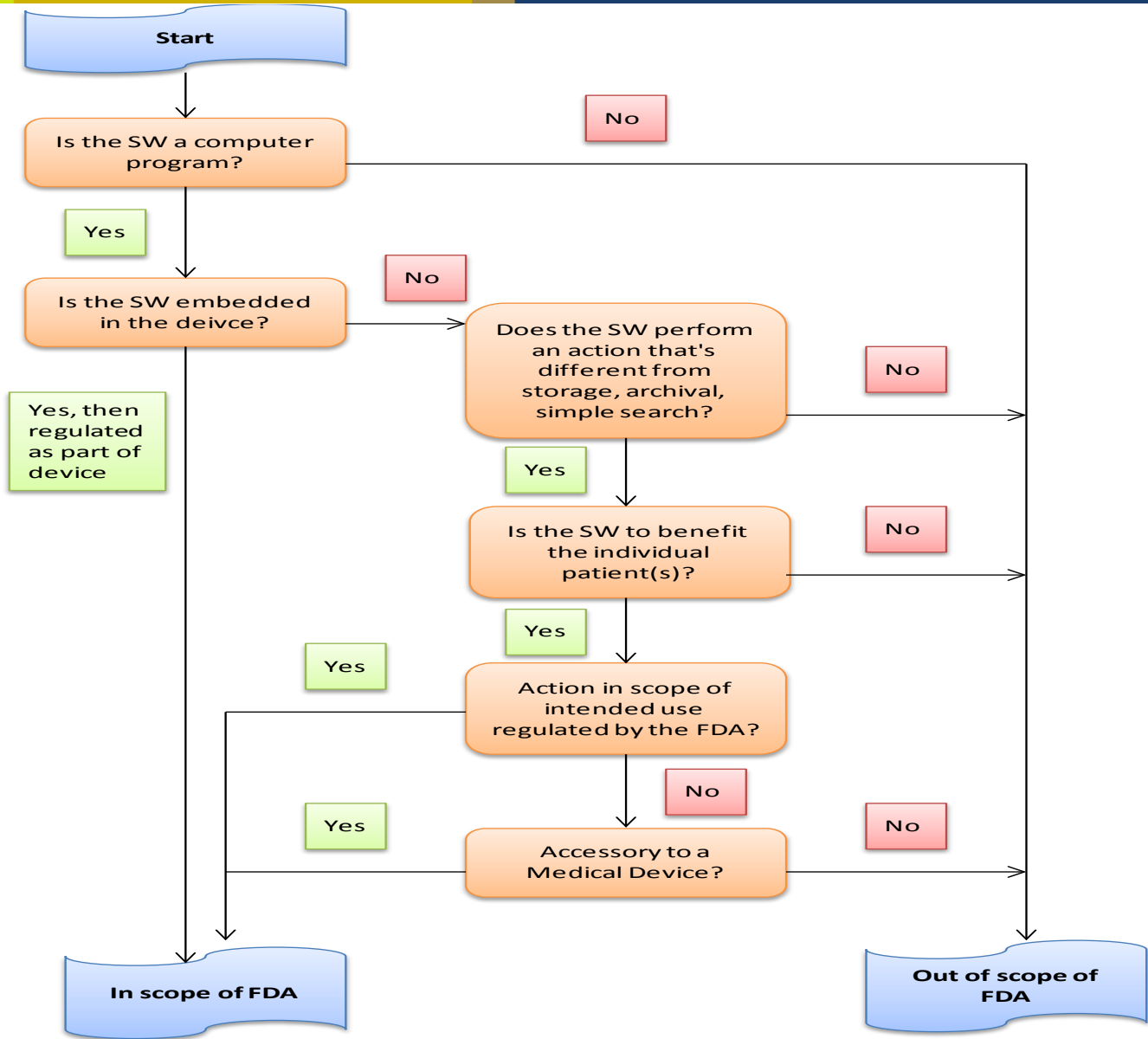
Examples of Mobile Medical Applications (cont.)

Apps that allow the user to input patient-specific information and using formulae or a processing algorithm output a patient specific result, diagnosis, or treatment recommendation:

- Apps that calculate parameters associated with the use of radioisotopes;
- Apps that assist with patient-specific dosing, e.g., radiation planning;
- Apps that act as a dosing calculators for a treatment regimen intended for a specific patient population (pediatrics).

Examples of Non-Mobile Medical Applications

- electronic "copies" of medical textbooks, teaching aids or reference materials, or are solely used to provide clinicians with training or reinforce training previously received;
- solely used to log, record, track, evaluate, or make decisions or suggestions related to developing or maintaining general health and wellness (non-therapeutic purpose);
- that only automate general office operations with functionalities that include billing, inventory, appointments, or insurance transactions;
- that are generic aids that assist users but are not commercially marketed for a specific medical indication;
- that perform the functionality of an electronic health record system or personal health record system.



Resources

- FDA Draft Guidance for Industry
Mobile Medical Applications



Questions?
Thank you!

