

Medical Devices: Software Functions and Mobile Apps

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FDA regulation of Software Functions and Mobile Medical Apps

- Focus of FDA Oversight
- FDA Enforcement Discretion
- Not a Medical Device

Focus of FDA Oversight

- Software functions that transform a mobile platform into a regulated medical device.
 - Example: A sensor attached to a mobile platform or tools within the mobile platform itself to record, view, or analyze eye movements for diagnosis of balance use disorders.
- Software functions that are used in active patient monitoring or to analyze patient specific medical device data.
 - Example: Acquire or process physiological signals that connect to bedside or cardiac monitors for active patient monitoring.

FDA Enforcement Discretion

- Meet definition of a medical device **AND** minimal risk
- Software functions that:
 - Help users self-manage their disease or condition without providing specific treatment suggestions
 - Automate simple tasks for health care providers
- Examples, software functions that:
 - use video and video games to motivate patients to do their physical therapy at home.
 - help patients with diagnosed psychiatric conditions maintain their behavioral coping skills by providing a Skill of the Day behavioral technique or audio message that to help when experiencing increased anxiety.

FDA Enforcement Discretion

- Does the Software Function/Mobile Medical App meet the Criteria of Non-Significant Risk Device?
 - NOT intended as an implant and does NOT present a potential for serious risk to the health, safety, or welfare of a subject;
 - NOT purported or represented to be for use supporting or sustaining human life and does NOT present a potential for serious risk to the health, safety, or welfare of a subject;
 - NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and does NOT present a potential for serious risk to the health, safety, or welfare of a subject; or
 - Otherwise does NOT present a potential for serious risk to the health, safety, or welfare of a subject.

Not a Medical Device

- Does not meet the definition of a medical device
- Intended for health care professionals to use as educational tools for medical training or to reinforce training previously received.
- Intended for individuals to record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness.
 - Example: Provides a tool to promote or encourage healthy eating, exercise, weight loss, or other activities generally related to a healthy lifestyle or wellness.

Questions?



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