



## Food and Drug Administration Draft Guidance on Mobile Medical Device Regulation/Classification

### Summary

On July 18<sup>th</sup>, 2011, the Food and Drug Administration [Centers for Devices and Radiological Health](#) (CDRH) released [draft policy guidance](#) announcing new mobile health information technology applications that FDA will consider regulating as medical devices. Of note, the FDA does **not** consider mobile applications that perform the functionality of an electronic health record system or a personal health record system. That doesn't mean those functionalities will not be addressed in future guidance.

Public comments will be due 90 days from publication in the Federal Register.

### Background on FDA Medical Device Regulatory Classification System

- **Class 1: Focus on Post-market Safety (Lowest Risk)**
  - Require Health IT device manufacturers to electronically register and list their Health IT devices, and submit Medical Device Reports to the FDA
  - Require Post-market Surveillance or tracking for selected higher risk devices
  - Lower risk Class 1 Devices are not subject to [510K approval](#)
- **Class 2: Focus on Quality Manufacturing and Post-market Safety**
  - Requires health IT device manufacturers to comply with Option requirements
  - Requires health IT device manufacturers to adhere to FDA's Quality System's Regulation (QSR)
  - Devices are subject to [510K approval](#)
- **Class 3: Traditional FDA Regulatory Framework (Premarket Approval)**
  - All health IT devices would be subject to traditional FDA premarket approval process
  - Applicants must receive premarket approval before marketing device
  - Products requiring premarket approval are Class III high risk devices that pose a significant risk of illness or injury
  - Premarket Approval Process requires submission of clinical data to support claims made by the device manufacturer
  - FDA Regulations provide 180 days to review the product and then approve or disapprove

**The following devices and applications are now classified by medical devices and are subject to FDA oversight.**

Regulation number	Medical Device	Device Class	Submission Type ID
876.1500(b)(2)	Accessories, Photographic, For Endoscope (Exclude Light Sources)	1	510(k) exempt
870.2770	Analyzer, Body Composition	2	510(k)
868.1890	Calculator, Drug Dose	2	510(k)
868.1890	Calculator, Predicted Values, Pulmonary Function	2	510(k)
868.1880	Calculator, Pulmonary Function Data	2	510(k)
868.1900	Calculator, Pulmonary Function Interpretation (Diagnostic)	2	510(k)
862.2100	Calculator/Data Processing Module, For Clinical Use	1	510(k) exempt
874.3310	Calibrator, Hearing Aid / Earphone And Analysis Systems	2	510(k)
878.4160	Camera, Cine, Microsurgical, With Audio	1	510(k) exempt
878.4160	Camera, Still, Microsurgical	1	510(k) exempt
878.4160	Camera, Television, Endoscopic, With Audio	1	510(k) exempt

870.1110	Computer, Blood-Pressure	2	510(k)
870.1425	Computer, Diagnostic, Programmable	2	510(k)
892.2020	Device, Communications, Images, Ophthalmic	1	510(k) exempt
892.2010	Device, Digital Image Storage, Radiological	1	510(k) exempt
892.2010	Device, Storage, Images, Ophthalmic	1	510(k) exempt
876.1500	Device, Telemedicine, Robotic	2	510(k)
862.2100	Digital Image, Storage And Communications, Non-Diagnostic, Laboratory Information System	1	510(k) exempt
892.2030	Digitizer, Image, Radiological	2	510(k)
892.2030	Digitizer, Images, Ophthalmic	2	510(k)
870.2800	Electrocardiograph, Ambulatory, With Analysis Algorithm	2	510(k)
882.1400	Electroencephalograph - Automatic Event Detection Software For Full-Montage Electroencephalograph	2	510(k)
882.1400	Electroencephalograph - Burst Suppression Detection Software For Electroencephalograph	2	510(k)
882.1400	Electroencephalograph - Index-Generating Electroencephalograph Software	2	510(k)
882.1400	Electroencephalograph - Non-Normalizing Quantitative Electroencephalograph Software	2	510(k)
882.1400	Electroencephalograph - Normalizing Quantitative Electroencephalograph Software	2	510(k)
882.1400	Electroencephalograph - Source Localization Software For Electroencephalograph Or Magnetoencephalograph	2	510(k)
876.1500	Endoscopic Video Imaging System/Component, Gastroenterology-Urology	2	510(k)
884.2225	Imager, Ultrasonic Obstetric-Gynecologic	2	510(k)
876.1500	Led Light Source	2	510(k)
878.4810	Light Based Over The Counter Wrinkle Reduction	2	510(k)
878.4810	Light Based Over-The-Counter Hair Removal	2	510(k)
880.6350	Light, Examination, Medical, Battery Powered	1	510(k) exempt
880.5580	Locator, Acupuncture Point	2	510(k)
870.1875(b)	Lung Sound Monitor	2	510(k)
886.5540	Magnifier, Hand-Held, Low-Vision	1	510(k) exempt
880.6315	Medication Management System, Remote	2	510(k)
884.6190	Microscope And Microscope Accessories, Reproduction, Assisted	1	510(k) exempt
868.2377	Monitor, Apnea, Home Use	2	510(k)
880.2400	Monitor, Bed Patient	1	510(k) exempt
884.2660	Monitor, Blood-Flow, Ultrasonic	2	510(k)
868.2375	Monitor, Breathing Frequency	2	510(k)
870.2300	Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm)	2	510(k)
886.1510	Monitor, Eye Movement, Diagnostic	2	510(k)
884.2660	Monitor, Fetal Doppler Ultrasound	2	510(k)
884.2730	Monitor, Heart Rate, Fetal, Non-Stress Test (Home Use)	2	510(k)
884.2660	Monitor, Heart Rate, Fetal, Ultrasonic	2	510(k)
884.2660	Monitor, Hemic Sound, Ultrasonic	2	510(k)
884.2640	Monitor, Phonocardiographic, Fetal	2	510(k)
870.2300	Monitor, Physiological, Patient(Without Arrhythmia Detection Or Alarms)	2	510(k)
870.2340	Monitor, St Segment	2	510(k)

884.2660	Monitor, Ultrasonic, Fetal	2	510(k)
884.2720	Monitor, Uterine Contraction, External (For Use In Clinic)	2	510(k)
878.4810	Over-The-Counter Powered Light Based Laser For Acne	2	510(k)
868.2550	Pneumotachometer	2	510(k)
878.4810	Powered Light Based Non-Laser Surgical Instrument	2	510(k)
870.2800	Recorder, Event, Implantable Cardiac,(Without Arrhythmia Detection)	2	510(k)
876.1725	Recorder, External, Pressure, Amplifier & Transducer	2	510(k)
890.5050	Reminder, Medication	1	510(k) exempt
880.2700	Scale, Stand-On, Patient	1	510(k) exempt
864.9175	Software, Blood Bank, Stand Alone Products	2	510(k)
886.5540	Spectacle Microscope, Low-Vision	1	510(k) exempt
868.1850	Spirometer, Monitoring (W/Wo Alarm)	2	510(k)
870.1875(b)	Stethoscope, Electronic	2	510(k)
868.1920	Stethoscope, Esophageal, With Electrical Conductors	2	510(k)
884.2900	Stethoscope, Fetal	1	510(k) exempt
876.4300	System, Alarm, Electrosurgical	2	510(k)
884.2990	System, Documentation, Breast Lesion	2	510(k)
892.2050	System, Image Processing, Radiological	2	510(k)
892.1560	System, Imaging, Optical Coherence Tomography (Oct)	2	510(k)
884.2800	System, Monitoring, For Progress Of Labor	2	510(k)
884.2740	System, Monitoring, Perinatal	2	510(k)
870.2300	System, Network And Communication, Physiological Monitors	2	510(k)
876.1500	System, Surgical, Computer Controlled Instrument	2	510(k)
864.9175	System, Test, Automated Blood Grouping And Antibody	2	510(k)
880.2910	Thermometer, Electronic, Clinical	2	510(k)
886.1930	Tonometer, Ac-Powered	2	510(k)
870.2920	Transmitters And Receivers, Electrocardiograph, Telephone	2	510(k)
870.2910	Transmitters And Receivers, Physiological Signal, Radiofrequency	2	510(k)

**SOURCE:** <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm>