# App purchases by Australian Consumers on mobile and handheld devices

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## Executive summary

This submission is in response to the release in December 2012 by the Commonwealth Consumer Affairs Advisory Council (CCAAC) of an Issues Paper: *App purchases by Australian consumers on mobile and handheld devices.* The Medical Technology Association of Australia (MTAA) welcomes the opportunity to comment on the paper and make specific recommendations. MTAA would like to see policy developed to manage the promotion of medical applications (apps) on smartphones that are marketed as medical devices but which are currently unregulated in the Australian market.

MTAA **recommends**:

- Regulation of smartphone medical apps that are intended by the developer to cure, treat, monitor or diagnose a medical condition.

This submission makes specific response to the question posed on Page 10 of the Issues Paper: *What features of the app market, if any, concern you? What actions do you think could be taken to improve consumers' experiences when making app and in-app purchases?*

## 1. About the Medical Technology Association of Australia (MTAA)

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

MTAA represents manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability. The range of medical technology is diverse with products ranging from consumable items such as syringes and wound dressings, through to high-technology implanted devices such as cardiac pacemakers. MTAA members distribute the majority of the non-pharmaceutical products used in the diagnosis and treatment of disease and disability in Australia. The medical technology industry had sales in Australia of more than $10.02 billion in 2010-11 and employs more than 19,000 people.

With the approaching tsunami of ageing people and the increase in the number of people with chronic diseases we need to find smarter ways to manage the health needs of Australians. In response to the looming demand for care we see the rapid adaptation of existing medical devices, and development of new applications for monitoring and treating health conditions in the home, that can respond to this demand. There has recently been an explosion of smart phone health and medical apps launch onto the market. These provide an innovative solution for self-management of a range of health conditions, however such apps are unregulated

and in some cases a smart phone app may claim to function as a medical device with potentially disastrous consequences.

## 2. Features of the app market of concern

### 2.1. Consumerization of medical devices

A wide range of health and medical applications (apps) can be downloaded for use on smartphones. Intel's Global Director of Health Innovation, Eric Dishman, uses the term "*consumerization of medical devices*" to explain how a simple object such as a phone can include embedded sensors and assist in healthcare. MobiHealthNews made the prediction that by August 2012 there would be 6,000 smartphone apps available to medical professionals and 13,000 health apps available to consumers on the iPhone alone. Many "medical" apps are misclassified and it is impossible to determine how many real (i.e., validated and reliable), medical apps actually exist. To date, only 75 mobile apps have received regulatory clearance from the Food and Drug Adminstration (FDA) in the US.

Medical apps for smartphones can be purchased by both medical professionals and consumers. There is concern about the use of unregulated medical apps by clinicians as a large number of mobile health apps are targeted at doctors to facilitate and improve patient health care, for example to perform calculations or assist with differential diagnosis. A separate concern is the purchase of apps by patients who are less likely to have the ability to assess whether an app is able to do what it claims. Consumers may have a preference for monitoring medical conditions using a smartphone app. For example, diabetics may prefer tracking glucose levels on a smartphone as it is less conspicuous than using a glucometer (glucose monitor). However, in terms of risk, a smartphone medical app for monitoring glucose is no different from a glucometer in terms of the seriousness of complications should the app fail to work as intended. Any app that provides medical advice may result in harm to the consumer if the advice is misleading or incorrect.

### 2.2. Safety of medical apps for smartphones

The Apple apps store for iPhone has thousands of "symptom checkers" and medical apps available to download (some at no cost). Smartphone health apps fall broadly into the categories of "medical" or "wellness"; an important distinction when determining whether an app needs to be regulated. The FDA issued draft guidance in July 2011 concerning the regulation of medical apps for smartphones. In late 2011 the FDA stated that it would assess the safety of *"a small subset of mobile medical applications that present a potential risk to patients if they do not work as intended"*. These are mobile applications which have an intended use similar to that of a medical device. The UK followed suit and the first smart phone app has been approved by the Medicines and Healthcare Products Regulatory Agency (MHRA). In January 2012 the Mersey Burns App was the first app registered with the MHRA as a Class 1 medical device (the app estimates burn area percentage and calculates fluids to be prescribed). Likewise, in Australia, the Therapeutic Goods Administration (TGA) has stated that it will act to regulate certain smartphone medical applications (none have been regualated to date).

Mobile medical apps are different from wellness apps (e.g., calorie counters). Medical apps are intended for *"curing, treating, seeking treatment for, mitigating, or diagnosing a specific disease, disorder, patient state or any specific, identifiable*

*health condition"*[1]. The distinction between wellness and medical apps can at times be unclear as many medical conditions can be helped using appropriate monitoring and other preventative measures. Medical apps designed to assist with prevention or monitoring can therefore fall into a grey area. They may have a significant impact on health but are not intended to "cure". In some cases an app may be marketed to function as a medical device but may not actually fulfill this function.

Medical apps can be used to help patients monitor their own health conditions at home (e.g., tracking heart rate or blood pressure). More sophisticated apps may replace visits to doctors or specialists and may be connected to devices such as glucometers used to assess blood sugar levels in diabetic patients. Some smartphones even contain sensors to measure physiological signals, for example, cardiovascular disease detectors that can be worn and detect disease in real time (Oresko et al., 2010). Additionally, laboratory on chip devices which are attached to smartphones can perform sample preparation and detection steps to run capillary electrophoresis and biomarker screening (Malic et al., 2010).

It is hard to know which medical apps live up to their claims or are of any use to the patient or doctor given that only a small number have received FDA clearance (see Appendix A). For example, the accuracy of smartphone apps for diagnosing melanoma is highly variable. A recent study found that 30% of melanomas were incorrectly classified as benign by smartphone apps (Wolf et al., 2013). Likewise, it is difficult to ascertain whether apps are based on scientific evidence, are reliable and have been developed without conflict of interest (e.g., an app developed by a pharmaceutical company recommending a specific drug treatment). The top five medical apps from Apple Inc. are listed below.

**Table 1:** Apple's top five medical apps of 2011[2].

| Name | Use |
|---|---|
| AirStrip Cardiology (AirStrip Technologies Inc) | FDA approved app that combines wireless mobile transmissions of ECG and automatic access to past data to enable decision making by cardiologists. The app can be used by doctors for remote monitoring. |
| The Skeletal System Pro II (NOVA Series) | The app allows the user to manipulate and view the skeletal system. The app is used for visualisation and reference purposes and includes an in-depth 3-D skeleton. |
| EyeDecide MD (Orca MD) | The app allows users to rotate the eye 360 degrees and see common eye conditions and treatments. |
| MobileMIM | FDA approved app that is used for viewing and displaying medical images obtained using MRI, PET, X-ray or ultrasound. |
| VueMe | Allows patients to store their medical images on the cloud and has an interface with the physician-centred Mobile MIM app. |

There is very little literature in regard to the safety of medical apps for smartphones. Safety research has looked at bacterial contamination of phones (Rodrigues & Brady, 2011) and physician distraction by smartphones (Katz-Sidlow et al., 2012), rather than the actual reliability of the medical apps being used by healthcare professionals. Smartphones are used by 85% of medical professionals. A survey of

[1] www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm
[2] www.imedicalapps.com/2011/12/apple-top-iphone-ipad-medical-apps-2011

clinicians found that 46% reported that they utilized smartphone apps with classification and treatment algorithms (Franko & Tirrell, 2011).

Anybody can create an app and it can be very lucrative to do so. A study assessing microbiology-themed apps found that only 34% been had been developed with the guidance of a medical expert (Visvanathan et al., 2012). In most cases there are no clinical trials and no process of academic peer review in the development of a medical app. Many have lengthy disclaimers and claim to diagnose or monitor various health conditions; however in most cases the apps are not subject to any validation or regulatory oversight.

Big business is often slow to embrace new technology. Personal computers and phone cameras are good examples of technologies where industry was slow to adopt but quality improved so dramatically and was adopted by consumers in such a short time that innovation could not be ignored. The Ernst & Young *Pulse of the Industry* (2012) report notes that Medtech has reached a similar juncture. Early adaptors are purchasing medical apps for smart phones that may cost less than a dollar. While they may not be able to do everything that medical devices can do, medical apps are becoming increasingly sophisticated and offer good functionality to consumers. Research shows that while consumers snap up apps, their product lifespan is short. Pinch Media found that only 30% of people purchasing iPhone apps use them the next day and that in the case of free apps the number is only 20%. After one month only 5% of iPhone app users were still using the app and after 90 days only 1%[3].

## 3. Regulation to improve consumer experiences associated with making app purchases

### 3.1. Food and Drug Administration (FDA) and regulation of medical apps

Medical apps have the potential to pose a risk to public health (although to date there are no well documented cases of them doing so). Turning a smartphone into a medical device has serious, potentially life threatening implications. Vos & Parker (2012) write that: *"Medical devices by their very nature have the potential to present a hazard – to be a source of harm in normal use, and more so if misused. Regulations are therefore a necessary instrument to safeguard users from undue and unnecessary risks and are based on the principle of mitigating, to an acceptable level, the potential of a device to cause harm"*.

In June 2012 Congress passed a bill that allows the FDA to regulate medical applications on smart phones (FDA Safety and Innovation Act). The previous year the FDA issued "Draft Guidance for Industry and Food and Drug Administration Staff; Mobile Medical Applications", which addresses how the FDA intends to apply its regulatory authorities to a subset of apps that the agency has termed "mobile medical apps". The guidelines clarify the types of mobile apps to which the FDA intends to apply its authority. The FDA defines a "mobile medical app" as a mobile app that meets the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); and either:

- is used as an accessory to a regulated medical device that is regulated by the FDA (i.e. an app that enables a doctor to view medical images and make a diagnosis); or

[3] www.slideshare.net/pinchmedia/iphone-appstore-secrets-pinch-media

- transforms a mobile platform into a regulated medical device (i.e. an application that turns a smartphone into an electrocardiography machine that detects abnormal heart beat or whether a patient is having a heart attack).

The FDA is concerned about those apps that pose identical or similar risk to public health as currently regulated medical devices if they fail to operate as intended. The components in a smartphone medical app may include a mobile phone, sensors, software and an associated network infrastructure, each of which could be classified as a device, component or accessory. The characteristic of a smartphone platform may pose a risk if, for example, a clinician is unable to clearly read an X-ray.

Apps that are *not* considered medical devices include[4]:

- Medical text and reference books such as teaching aids or materials
- Mobile apps that are used only to record, track, evaluate, or make decisions or suggestions in regard to general health and wellness. This is in the case where those decisions, suggestions, recommendations are NOT intended for disease treatment or any identifiable health condition. These types of apps include calorie counters, or decision tools relating to general health and wellness
- Mobile apps that automate general office functions such as billing, appointments, collecting patient history, and apps that replace paper-based entry
- Mobile apps that are generic aids to assist users (i.e. a magnifying glass) but are not marketed for a specific medical purpose
- Mobile apps for personal or electronic health record systems.

Examples of the types of applications for which the FDA will provide oversight are shown in Table 2 (see Appendix B for a full list of examples).

**Table 2:** Mobile Medical Applications for which FDA will apply regulatory oversight[5].

| Description | Examples |
|---|---|
| Mobile applications that are an extension of one or more medical device(s) or displaying, storing, analyzing, or transmitting patient-specific medical device data | - Remote display of data from bedside monitors<br>- Display of previously stored EEG waveforms<br>- Display of medical images directly from a Picture Archiving and Communication System (PACS) server<br>- Control of inflation/deflation of a blood pressure cuff<br>- Control of the delivery of insulin from an insulin pump. |
| Mobile applications that transform the mobile platform into a medical device by using attachment, display screens, or sensors, or by including functionalities similar to those of currently regulated medical devices | - Attachment of a transducer to a mobile platform to function as a stethoscope<br>- Attachment of a blood glucose strip reader to a mobile platform to function as a glucose meter<br>- Attachment of electrocardiograph (ECG) electrodes to a mobile platform to measure, |

[4] FDA Guidance Document: Draft Guidance for Industry and Food and Drug Administration Staff. Mobile Medical Applications. Document issued on July 21, 2011

[5] from Barton, 2012

| | |
|---|---|
| | store and display ECG signals<br>- App that uses the built-in accelerometer on a mobile platform to collect motion information to collect motion information for monitoring sleep apnea. |
| Mobile applications that allow the user to input patient-specific information and through the use of formulae or processing algorithms, output a patient-specific result, diagnosis, or treatment recommendation to be used in clinical practice or to assist in clinical decisions | - Mobile applications that provide a questionnaire for collecting patient-specific lab results and either: (1) compute the prognosis of a particular condition or disease; (2) perform calculations that result in an index or score; (3) calculate dosage for a specific medication or radiation treatment; or (4) provide recommendations that aid a clinician in making a diagnosis of selecting a specific treatment for a patient. |

The FDA will address separately those medical apps intended to analyze, process or interpret data from more than one medical device. For example, analysis of Class I device information in conjunction with demographic information may result in interpretation of an acute patient condition which presents higher risk than the connected Class I device.

## 3.2. Therapeutic Goods Administration (TGA) and regulation of medical apps

Medical devices are regulated by the Therapeutic Goods Administration (TGA) in Australia and must be included on the Australian Register of Therapeutic Goods (ARTG). The TGA has stated that it will regulate health apps for smartphones as the need arises. The TGA's current medical device regulatory framework provides for regulation of software for therapeutic purposes. There are some medical software tools listed including physician management and sleep assessment software. There are no current listings for medical apps for smartphones on the ARTG. The TGA has stated that it will undertake an independent investigation if a complaint is lodged about a medical app or an-add on.

Medical devices have the potential to present a hazard, in particular if they are used incorrectly. Regulations are based on the principle of mitigating, to an acceptable level, the potential of a device to cause harm. Devices are classified according to the risk they present to the human body. Risk determines the level of regulatory oversight, including the level of evidence required before the device can be approved for supply. The general classification for medical devices in Australia is as follows:

| **Classification** | **Risk Level and Regulatory Requirements** | **Examples** |
|---|---|---|
| Class I | Low | wheelchairs, ostomy pouches, crutches |
| Class IIa | Low to Medium | electrocardiographs, hearing aids |
| Class IIb | Medium to High | non-implantable insulin infusion pumps, long term urinary catheters |
| Class III | High | heart valves, aneurysm clips, cortical electrodes, devices containing medicines |
| AIMDs | High | pacemakers, neurostimulators, cochlear implants |

The manufacturer's intended use of a medical app for a smartphone will determine its risk level and regulatory requirements. Medical devices are required to have varying levels of clinical evidence depending on their classification. Manufacturers of all medical devices have to undertake risk analyses to determine the residual risk when the device is used. Clinical evidence has to be developed if any residual risk cannot be eliminated so that the manufacturer can demonstrate that the benefit of using the device outweighs any residual risk. For Class I items, clinical evidence may therefore not be needed if it is possible to determine that benefit outweighs risk.

All medical device manufacturers and sponsors have to comply with post-market vigilance and monitoring requirements. Currently there is no process to review medical apps before they are released. There are a wide variety of medical apps, meaning that there are a wide variety of risks, for example medication names and doses may be uploaded incorrectly, glucose levels may be recorded incorrectly or drug allergies may be misinterpreted. The TGA's role is limited to regulation of medical devices and clinical software. In many cases medical apps represent a grey area and it is recommended that app developers consult regulatory authorities to determine whether medical device regulations apply.

A recent article in the Medical Journal of Australia highlights concerns around the need for regulation of clinical software on personal mobile devices. The article focuses on apps used by health professionals and notes that *"In the absence of regulatory guidelines, physicians and health organisation need to be cautious about their use of this software, which, when linked to error, may lead to medicolegal consequences"* (Fernando, 2012, p. 437).

## 3.3. Privacy/data security concerns

There are concerns that software developers are creating apps in order to access medical information. Juanita Fernando, from the Faculty of Medicine at Monash University in Melbourne notes that medical information theft is the fastest growing area of cybercrime in Australia[6]. When a consumer makes a purchase of a health or medical app they are likely to enter their names, addresses and phone numbers. Short message service (SMS) information is not difficult to intercept and medical apps can contain large amounts of confidential information. In many cases consumers do not read the fine print that states how their information can be used. In some cases apps can access the content of SMS messages and address books. Apps may be developed internationally by individuals not operating within the confines of Australian privacy laws.

The lack of legal certainty around the use of clinical software (e.g., MedCalc or iSthethoscope) on personal mobile devices such as smart phones and tablets exposes healthcare professionals to risk (e.g., ensuring data security). Legislation in Australia does not address security risks such as monitoring activity on smartphones or security and transmission of user logins. Regulations are needed to mitigate risk as it is possible that medical apps could be feeding information about the user to third parties (e.g., pharmaceutical or market-research companies).

All 3G, 4G and tablet devices have the potential to harvest private information. A 2010 study by the Wall Street Journal reported that 64% of smartphone apps transmitted the unique device ID of the phone to other companies without user consent or knowledge, 47% transmitted the phone's location and 5% sent personal

[6] See: http://www.theage.com.au/digital-life/smartphone-apps/an-app-a-day-keeps-the-doctor-away-20121220-2bp9s.html#ixzz2GyJaPStZ

details such as gender and age[7]. Australian doctors load medical apps that may enable information to be collected by third parties. In many cases it is up to the user to change their settings and "opt out" in order to control what information can be sent by their devices. Many apps require users to click to agree to (lengthy) terms and conditions prior to download. The issues paper released by the CCAAC points out that only 7% of app users in the UK pay attention to the terms and conditions when making online purchases[8].

One of the greatest concerns over the use of smartphone apps in clinical care is the risk of breaching patients' confidentiality. Current regulations protecting health information stored electronically do not cover health information in medical apps. It is essential to ensure that third-party apps on a smartphone will not compromise the privacy and security of health information. There are a number of issues around the privacy of patient data, and the potential for viruses or malware to distort device functioning that need to be taken into consideration.

Neither Apple or Google has privacy policies as a requirement for app manufacturers. Free apps may be sponsored by companies which have an interest in tracking information such as medication usage. Free apps may also be a subversive way of influencing medical professionals. Medical apps that are developed by third parties or companies should publish disclosures.

## 4. The need for regulation and standards

Given that there are thousands of medical apps for smartphones, with more entering the market every day, the role of agencies such as the TGA to regulate is an immense task. The GSMA (Groupe Speciale Mobile) and the Continua Health Alliance have released a policy position paper on mobile device regulation. They stress the importance of industry involvement in developing guidelines and ensuring that regulations do not inadvertently stifle innovation and hold back new technologies from reaching market. They outline key principles such as:

- "Intended use" is a cornerstone of device regulation
- Risk assessment and medical device classification
- Standards
- The role of the manufacturer
- Device accessory and component
- Hardware, software and network infrastructure.

### 4.1. Implications of regulation: intended use

A medical app on a smartphone that monitors heart rate or blood pressure is a Class I medical device even if it does not make specific health related claims. Many medical apps make specific claims to monitor or treat various health conditions and may be considered medical devices for regulatory purposes. If an app is marketed as having a therapeutic use and claims to treat a medical condition it is a medical device.

Device regulations differ between countries; however the U.S., E.U. and Australia all share the governing principle of "Intended use". The Therapeutic Goods (Medical Devices) Regulations 2002 defines "intended purpose" as:

[7] http://online.wsj.com/article/SB10001424052748704694004576020083703574602.html
[8] www.guardian.co.uk/money/2011/may/11/terms-conditions-small-print-big-problems

" … the purpose for which the manufacturer of the device intends it to be used, as stated in:

(a) the information provided with the device; or
(b) the instructions for the use of the device; or
(c) any advertising material applying to the device."

This means that the decision on whether to apply a regulation to a device or service is based on the intended purpose of the product and its mode of action. This relieves mobile phone manufacturers and vendors of the burden of medical device regulation as in most instances a mobile phone is not intended to be a medical device, despite the fact that medical apps can be run on them. In most cases, the writer/developer of the medical app is considered the manufacturer and carries the burden of compliance based on intended use.

The principle of intended use determines whether an app meets the definition of a medical device. This is why the wording in claims and advertising material is important. There are cases where medical apps may not contain any components used to monitor or treat a health condition (e.g., sensors) but may claim to have a therapeutic purpose. A mobile app is a device if the intended use of the app is to diagnose disease or other conditions, or to cure, mitigate, treat, or prevent disease, or is intended to affect the structure or any function of the body. If an app is intended for use in performing a medical device function such as analyzing glucose meter readings, it is a medical device (platform is irrelevant).

## 4.2. Implications of regulation: post market surveillance

A large number of apps can be purchased online that are classified as "medical" or "wellness" but may or may not be considered medical devices. Anyone who purchases a medical app should be aware of regulations and should be informed of the amount of scrutiny an app has been subjected to in order to assess it. Manufacturers should clearly label products and include this information.

If a company/individual places a medical app that is a medical device on the market, that company/individual must comply with the appropriate medical device regulations. This holds, irrespective of route to market. Post market surveillance, monitoring and acting upon complaints or adverse events are all the responsibility of the manufacturer (in most cases, the distributor or components manufacturer is not responsible). The customer must be able to contact the manufacturer (and vice versa - should there be any issues the manufacturer should have a way of notifying the customer).

Most apps are purchased online, downloaded and used offline. Recall of a faulty or erroneous medical app is difficult. A manufacturer is able to remove an app from an online app store, however this will only stop new downloads. The manufacturer is not able to directly remove an app from a smartphone. In most cases this must be done by the user (in extremely limited cases an app can be removed remotely). This means that any app which has been recalled may still be in use by thousands of people. There is no guidance and no official standards on the best way to recall a potentially dangerous medical app.

## 4.3. Market driven controls

It is only a matter of time before medical errors caused by incorrect use of medical apps gain major media attention. In 2011 Pfizer recalled a rheumatology calculator app because it gave erroneous scores for specific markers of disease activity[9]. The Federal Trade Commission (FTC) has removed two fraudulent apps from market in the US. The mobile apps "AcneApp" and "AcnePwer" both claimed to be able to treat acne using coloured lights emitted from the smartphone. The developers of "AcneApp" claimed the app was developed by a dermatologist and, according to a study reported in the British Journal of Dermatology, reduced blemishes by 76%. The charges brought by the FTC barred the developers from making unsubstantiated claims and misrepresenting scientific data. Both companies were fined.

There are some market-driven controls influencing the sale of medical apps. The first is customer reviews which may influence purchase. The second is the risk of product liability litigation (particularly in the U.S). This risk means that medical app manufacturers will need to document risk assessment to some level. Finally medical experts are beginning to apply the process of peer review to medical apps (Visser & Buijink, 2012, Vollebregt, 2011). It is important that physicians and medical institutions have processes to ensure that they use only those apps that are reliable, evidence-based, have been peer reviewed, are up-to-date and that they are trained to use.

Apple Inc. now has a Director of Medical Marketing. Medical apps are big business and the health app market is believed to be worth about $718 million[10]. A U.S company, Happtique (a subsidiary of the Greater New York Hospital Association), has developed an online store and app certification system specifically for mobile health applications and is developing a system to enable doctors to "prescribe" apps to patients[11].

Healthcare professionals and consumers need to be wary when using health apps. It is likely that the next few years will see a number of developments that will enhance the safety of medical apps for smartphones. The challenge will be developing regulations that ensure that risks are reduced without stifling innovation. There are a range of actions that can be taken by consumers, industry and government to ensure the safety of medical apps for smartphones.



[9] Pfizer Ltd. Pfizer rheumatology calculator. Iphone/Android application. Important information. 14 October 2011. http://www.mhra.gov.uk/home/groups/fsn/documents/fieldsafetynotice/con137658.pdf
[10] www.research2guidance.com/the-market-for-mhealth-application-reached-us-718-million-in-2011
[11] see www.happtique.com

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## Appendix A - Examples of FDA regulated medical apps (devices)

FDA databases can be accessed through the following link:
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm.

| 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 | 2 | 510(k) |

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|---|---|---|---|
| | Quantitative Electroencephalograph Software | | |
| 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) |

## Appendix B – FDA examples of mobile medical apps[12]

This Appendix provides examples of medical apps for smartphones. There may be other apps not included in this list that might also constitute medical apps.

Medical apps that are extensions of regulated medical device for purposes of controlling the medical device or for the purpose of displaying, storing, analyzing, or transmitting patient-specific medical device data:

- Apps that allow the user to view medical images on a mobile platform and perform an analysis or process for diagnosis;
- Apps that connect to DICOM medical image servers and provide processing functions such as pan, zoom, measurement, auto contrasting, automatic detection of features, and other similar functionality;
- Apps that analyze, assess, or interpret electrocardiogram or electroencephalogram data;
- Apps that connect the mobile platform to vital signs monitors, bedside monitors, cardiac monitors, or other similar devices to:
  - Be used as a central viewing station for display;
  - Remotely access vital sign measurements of patients at home;
  - Be used in displaying and viewing digital images, including digital mammography, for review and analysis by trained medical practitioners;
  - Record arterial oxygen saturation and pulse rate of adult and pediatric patients inside hospitals and activate an alarm based on changes in levels;
  - Remotely review other standard or critical real-time numeric data from labor and delivery;
  - Perform remote Holter monitoring;
  - Connect to medical imaging devices for displaying, processing or storing medical images;
  - Wirelessly connect to medical devices and can relay or generate alarms;
  - Perform remote control, setting changes, or readout via wireless links such as programming or controlling a hearing aid system or implantable or body worn medical device.
- Apps that are used as patient screening tools for blood transfusion (extension of Blood Establishment Computer Software (BECS)) or other biologics;
- Apps that connect to a home use diagnostic medical device such as a 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;
- Apps that control a blood-pressure cuff connected to a mobile platform to inflate the cuff and measure a person's blood pressure; or
- Apps that act as wireless remote controls or synchronization devices for MRI or X-Ray machines.

[12] From FDA Draft Guidance for Industry and Food and Drug Administration Staff

Mobile medical apps that transform or make the mobile platform into a regulated medical device by using attachments or sensors or similar medical device functions:

- Apps that attach EKG/ECG leads to a mobile platform to collect/analyze/monitor EKG/ECG signals;
- Apps that connect wirelessly to a blood glucose tester to display, calculate, trend, convert, or download results to a PDA;
- Apps that generate sine signals from 125Hz to 8kHz (8 steps) to check the user's hearing;
- Apps that act as a blood glucose meter by using an attachment to a mobile platform;
- Apps that act as an electronic stethoscope by connecting (either via wire or wirelessly) to an external sensor to record, manipulate, or measure sound waves;
- Apps that use the mobile platform with or without a sound transducer (microphone) to act as an electronic stethoscope to amplify heart, lung, blood vessel, enteral, and other body sounds;
- Apps that use the built-in accelerometer or other similar sensors in a mobile platform to monitor the user's movement to determine conditions such as sleep apnea, sleep phase, fall detection, or detect motion related to other conditions or diseases or to measure heart rate;
- Apps that use the light source from a mobile platform to cure and treat specific conditions, such as acne;
- Apps that attach sensors to a mobile platform to measure blood glucose, electrocardiograph, or other similar functions;
- Apps that use a mobile platform's built in features such as light, vibrations, camera, or other similar sources to perform medical functions;
- Apps that use a mobile platform to upload electroencephalograph (EEG) recordings and automatically detect seizures;
- Apps that use a mobile platform to record response time and accuracy of patients completing a cognitive task and/or automatically score or interpret cognitive testing results;
- Apps that use pictures and sound to diagnose conditions by comparing to previously determined diagnoses of images, symptoms, sounds, or other physiological measurements; or
- Apps that use a mobile platform in determining blood donor eligibility prior to collection of blood or blood components.

Mobile medical 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 that is used in clinical practice or to assist in making clinical decisions:

- Apps that perform calculations intended to be used by clinicians for automating tasks, such as:
    - eGFR with CKD-Epi, Cockcroft-Gault, and MDRD;
    - A-a gradient, etc.
- Apps that act as calculators or utilize algorithms to produce an index, score, scale, or other similar calculations (e.g., Glasgow Coma Scale, pain index, Apgar score, NIH stroke scale, etc.);
- Apps that calculate parameters associated with the use of radioisotopes;
- Apps that calculate the amount of chemotherapy needed based on the patient's Body Surface Area;

- Apps that assist with patient-specific dosing, e.g., radiation planning;
- Apps that calculate Warfarin Loading and Warfarin Maintenance doses for different anti-coagulation therapies based on nomograms;
- Apps that act as calculators to determine the maximum dosage of local anesthesia based on a patient's weight and age; or
- Apps that calculate Osteoporosis Risk Assessment by Composite Linear Estimate (ORACLE score).
- Apps that collect blood glucose readings and caloric intake to help manage diabetes by calculating pre-meal insulin dose (Bolus) or Basal adjustments; or
- Apps that act as a dosing calculators for a treatment regimen intended for a specific patient population (pediatrics);
- Apps that define disease stage or progression, and provide a prognosis of a medical condition or predict a patient's response to treatment based on a analysis of physiological, laboratory, and other data; or
- Apps that provide differential diagnosis tools for a clinician to systematically compare and contrast clinical findings (symptoms/ results, etc.) to arrive at possible diagnosis for a patient.