

# Tele-Medicine

## A Likely Future for US

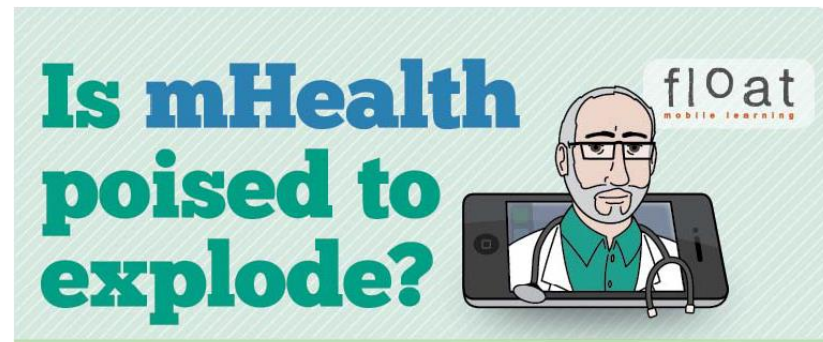
RTC Tele-Medicine Panel

April 15, 2015

# Tele-Medicine, It's Personal

- Cystic Fibrosis - Affirmation from Health Pro's regarding home care and increased wellness monitoring for 3 Grandkids who have CF.
- Type II Diabetes – Better Monitoring, Encouragement, and Facts to help with Diet & Blood sugar issues.

# The Promise for Tele-Medicine - Facts



There are currently more than 320 million mobile phones in the U.S., and 1.7 million hospital beds. That's about **185 phones for every bed!**

The emerging field of Mobile Health (mHealth) has enabled consumers to use smartphone technology to answer their own health-related questions with the quick tap of a touchscreen. **Here's a look at Mobile Health, and the impact it's making on our culture and our well-being:**



**1 billion** visits to physicians' offices were made by Americans in 2011.



**40%** of doctors believe that **mobile health technologies can reduce the number of office visits.**

**80%**

of doctors use **smartphones & medical apps.**



# Setting the Technology Stage for Tele-Medicine

There are more than  
**10,000**  
medical/healthcare  
apps available in  
Apple's iTunes App  
Store.



It's the **3<sup>rd</sup> fastest-growing app category** for both iPhone & Android phones!



of US consumers are interested in **Mobile Health solutions.**



of doctors would like their patients to **monitor their health at home**, particularly their weight, blood sugar, & vital signs.

Doctors are also

**250%**

more likely to own a **tablet** than other consumers.



**56%** of doctors who use mobile devices say they **expedite decision-making.**

**40%** say they **decrease time spent on administration.**

# Facts about apps for Smart Phones

## mHealth examples & uses

### Wellness

**Macaw** can transform a smartphone into a personal health hub, connecting an individual's health apps & wireless devices into a single, complete app for comprehensive tracking.



### Homecare Emergencies

**Welldoc** is a set of programs & apps that can cut hospital & ER visits in half by having patients monitor & manage their own chronic diseases.

**iCPR** is an app that helps anyone become a CPR expert. Use your smartphone to detect the rate and count of chest compressions.

## mHealth isn't confined to just your smartphone or tablet.

These devices connect to and sync with your smartphone to help you monitor your health/wellness & fitness performance.

### iStethoscope

iPhone app with built-in microphone lets you **record and play back a heart-beat.**



### iHealthBPM

Its self-monitoring system lets users **test, track, & record their blood pressure,** and share the results.

### Nike Plus

Turn your smartphone into your **personal fitness trainer.**

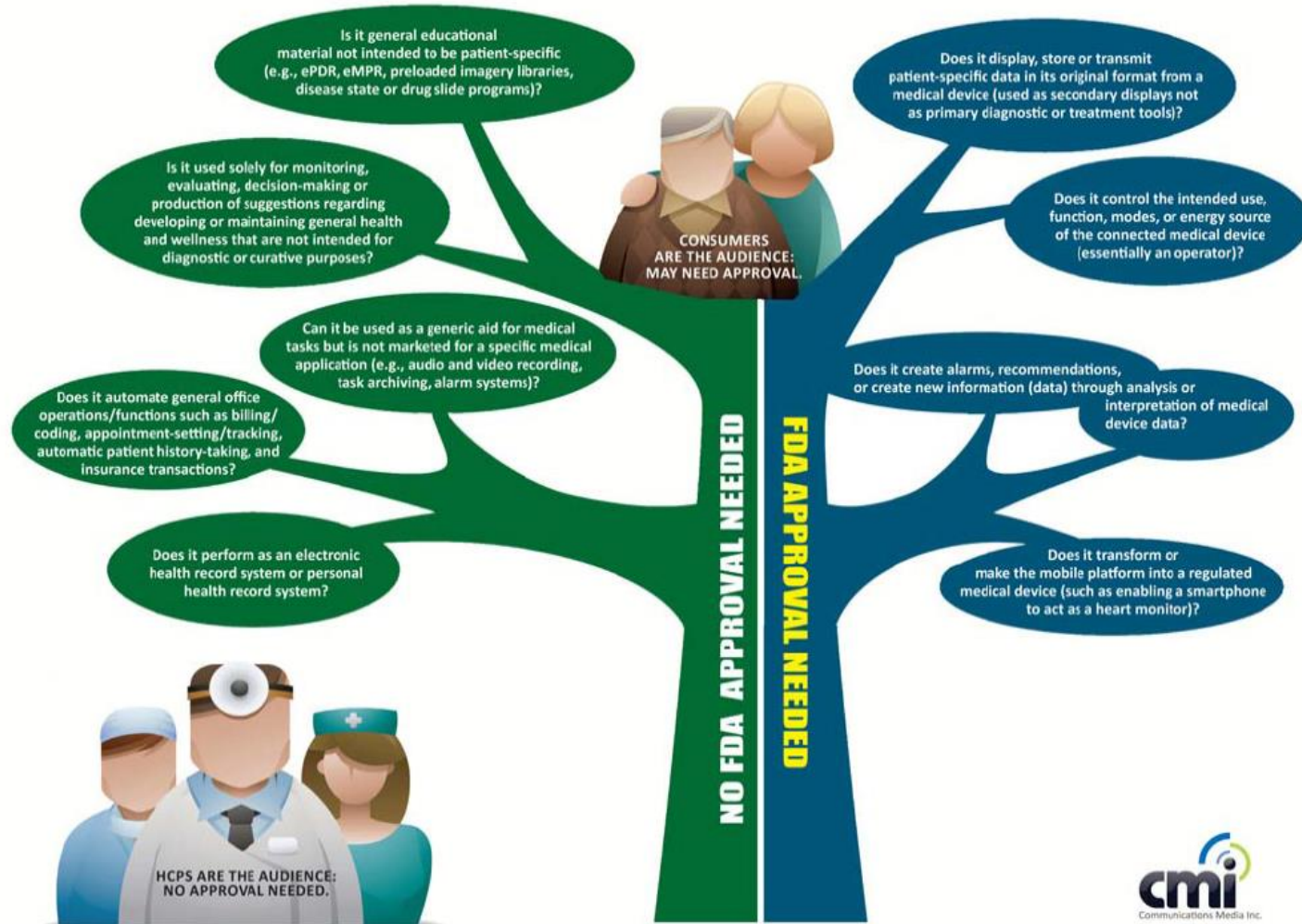


For more information, visit [FloatLearning.com/mhealth](http://FloatLearning.com/mhealth).

**float**  
mobile learning

# Tele-Medicine Policy – FDA

## Does the FDA Need to Approve My Mobile Medical App?





SEARCH

Most Popular Searches

- Home
- Food
- Drugs
- Medical Devices
- Radiation-Emitting Products
- Vaccines, Blood & Biologics
- Animal & Veterinary
- Cosmetics
- Tobacco Products

## Medical Devices

- Home
- Medical Devices
- Resources for You (Medical Devices)
- Industry (Medical Devices)



### Resources for You (Medical Devices)

Industry (Medical Devices)

Letters to Industry

CDRH Outreach Emails

## Letter to Biosense Technologies Private Limited concerning the uChek Urine Analyzer

### It Has Come to Our Attention Letter

Myshkin Ingawale  
C/O Sumit Singh  
Biosense Technologies Private Limited  
212 Hockney Avenue  
MOUNTAIN VIEW, CA 94041  
Document Number: GEN1300289

Dear Myshkin Ingawale:

It has come to our attention that you are currently marketing the uChek Urine analyzer, which is intended for use with Siemens Multistix SG10, Siemens Multistix SG, Siemens Uristix, Bayer Diastix, and Bayer Keto-Diastix reagent strips for the qualitative and semi-quantitative determination of urine analytes including glucose, urobilinogen, pH, ketone, blood, protein, bilirubin, nitrite, leukocyte, and specific gravity. The uChek Urine analyzer appears to meet the definition of a device as that term is defined in section 201(h) of the Federal Food Drug and Cosmetic Act.

Please note that though the types of urinalysis dipsticks you reference for use with your application are cleared, they are only cleared when interpreted by direct visual reading. Since your app allows a mobile phone to analyze the dipsticks, the phone and device as a whole functions as an automated strip reader. When these dipsticks are read by an automated strip reader, the dipsticks require new clearance as part of the test system. Therefore, any company intending to promote their device for use in analyzing, reading, and/or interpreting these dipsticks need to obtain clearance for the entire urinalysis test system (i.e., the strip reader and the test strips, as used together). For an example of this type of device system, and a summary of the type of data used to support clearance of the system, see the decision summary for k111221 ([http://www.accessdata.fda.gov/cdrh\\_docs/reviews/K111221.pdf](http://www.accessdata.fda.gov/cdrh_docs/reviews/K111221.pdf)).

We have conducted a review of our files, and have been unable to identify any Food and Drug Administration (FDA) clearance number for the uChek Urine analyzer. We request that you provide us with the FDA clearance number for the uChek Urine analyzer. If you do not believe that you are required to obtain FDA clearance for

# The FDA challenge – The Technology

## FDA Apprehension

- Critical distinction between health apps and wellness apps
  - Health apps – mobile software that diagnose, track or treat disease
    - Can monitor patients outside of the hospital
    - Track vitals , Analyze medical images for physicians
- Wellness apps – enhance or track the overall health of the user.

Many health and wellness apps can have **serious consequences on patient health.**



# FDA Policy – Just one complexity

FDA Regulation:

Certification mandated for APPs that are used for:

- Diagnosing critical conditions
- Regulating drug delivery
- Monitoring critical care factors such as blood oxygen levels
- Mobile software that diagnose, track or treat disease

# Tele-Medicine Questions

- Prescriptions for Tele-Medicine Devices - Who pays for what?  
Medicare, Medicaid, Insurance Carriers, Individuals
- Role of FDA? Is it Safe.
- State Licensing of Physicians
- Connectivity & Digital Divide
- HIPPA vs Open Access
- Liability (Care Providers, Device Manufacturers, etc.)