



On Behalf of:

InTouch Health

White Paper

FDA Regulation of Mobile Health Technologies

The Current Regulatory Framework as Applied to
InTouch Health's Telemedicine Solution

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I. EXECUTIVE SUMMARY

Mobile health and telemedicine products (including software associated with these technologies) have for many years been regulated as medical devices by the U.S. Food and Drug Administration (FDA). More recently, the FDA has begun developing a regulatory framework specific to mobile health and telemedicine technologies. Through this work, the FDA has clarified—and expanded—how these technologies are regulated. This white paper summarizes the current FDA framework for mobile health and telemedicine products and how it applies to InTouch Health’s Telemedicine Solution.

FDA regulation of medical devices depends on the risk associated with the product. Class I devices are associated with low risk and, therefore, involve the least burdensome regulatory oversight. Class II and III devices involve increasingly greater regulatory requirements as devices that fall within these categories are associated with moderate or high risk. Mobile health and telemedicine devices fall into each of these classifications, and devices involved in active patient monitoring fall within Class II or III.

The InTouch Health Telemedicine Solution is a range of mobile, robotic telecommunications devices that enable transmission and storage of real-time audio/video and other patient data as well as active patient monitoring. It has been cleared by FDA as a Class II medical device.

II. REGULATORY BACKGROUND

A. RISK-BASED REGULATION OF MEDICAL DEVICES

FDA’s mission includes protecting the public health by assuring the safety, efficacy and security of medical devices.¹ This mission is expansive, and FDA takes a correspondingly expansive approach in its regulation of medical devices in order to achieve it.²

The FDA regulates medical devices based on the risk and innovation associated with the device. Under this scheme, the FDA designates devices as Class I (lowest risk), Class II (moderate risk), or Class III (highest risk). These classes correspond with the level of regulation that applies to the device. Generally, Class I devices can enter the market without any pre-approval or clearance by FDA, while Class II devices must comply with such **premarket notification requirements** including a **510(k) submission**.³ This is in addition to other regulatory requirements such as quality system requirements and medical device reporting,⁴ among others. Finally, Class III devices must submit and obtain approval for a **premarket approval application (“PMA”)** before they can be sold in the marketplace.⁵ In general, a PMA takes longer, is more expensive, and requires more clinical data than a 510(k) submission.

FDA has established the classification for many medical devices by regulation. Devices that do not have their classification established are often new and novel devices. These are regulated as Class III, unless the manufacturer can demonstrate substantial equivalence to an existing Class II device.

¹ U.S. Food & Drug Admin., *What We Do*, <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last visited Sept. 27, 2011).

² See 21 U.S.C. § 331(a) (prohibiting the “introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded”).

³ See 21 C.F.R. pt. 807.

⁴ *Id.* pt. 803.

⁵ *Id.* pt. 814.

Mobile health technologies, including telemedicine products, run the gamut of Class I, II, and III. As explained in detail below, FDA recently established a new class of mobile health devices—Medical Device Data Systems—as Class I devices exempt from premarket notification requirements.⁶

FDA has classified many patient monitoring devices as Class II devices, including general hospital and personal use monitoring devices,⁷ anesthesiology monitoring devices,⁸ obstetrical and gynecological monitoring devices,⁹ and cardiovascular monitoring devices.¹⁰ Telemedicine devices with similar patient monitoring uses (e.g., telestroke, tele-ICU, among others) also are typically regulated as Class II devices.¹¹ **InTouch Health's Telemedicine Solution is regulated as a Class II device, and like most other Class II devices, is subject to 510(k) premarket notification requirements.**

Devices that fall outside of these and other classifications are regulated as Class III devices, unless and until FDA is persuaded that the device warrants a different classification.

B. RECENT TRENDS IN REGULATION OF MOBILE HEALTH DEVICES

FDA's attention is focused on the growing area of mobile health technologies. Here we describe some major developments that occurred recently: (1) the **medical device data systems (MDDS)** regulation; (2) the mobile medical application draft guidance; and (3) FDA statements on clinical decision support software.

1. The MDDS Regulation and Its Impact

In February 2011, FDA issued a regulation for MDDS devices. We recite the definition of an MDDS here for convenience:

[A] device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices: (i) The **electronic transfer** of medical device data; (ii) The **electronic storage** of medical device data; (iii) The **electronic conversion** of medical device data from one format to another format **in accordance with a preset specification**; or (iv) The **electronic display** of **medical device data**.¹²

In summary, an MDDS is a device through which **medical device data are passively transferred or communicated**.¹³ They do **not** modify, interpret, or add value to the data or the display of the data.¹⁴

What are **medical device data**? Any electronic data that are available directly from a medical device or that were obtained originally from a medical device are considered medical device data.¹⁵

⁶ *Id.* § 880.6310(b).

⁷ *Id.* §§ 880.2200–.2930.

⁸ *Id.* §§ 868.2025–.2900.

⁹ *Id.* §§ 884.2050–.2990.

¹⁰ *Id.* §§ 870.2050–.2920.

¹¹ In some situations where no classification exists or no substantially equivalent Class II devices exist, these devices might be regulated as Class III devices.

¹² See, e.g., *Medical Devices; Medical Device Data Systems*, 76 Fed. Reg. 8637, 8649 (Feb. 15, 2011) (to be codified at 21 C.F.R. § 880.6310), available at <http://www.gpo.gov/fdsys/pkg/FR-2011-02-15/pdf/2011-3321.pdf> (emphasis added).

¹³ *Id.* at 8640.

¹⁴ *Id.* at 8641.

Data that are manually entered into a medical device are not medical device data unless the manually entered data are subsequently transmitted from a medical device as electronic data.¹⁶

Importantly, MDDS devices may include software or electrical hardware but do not include devices intended to be used in connection with **active patient monitoring**.¹⁷ A device that involves **active patient monitoring** is any device that:

- Is intended to be relied upon in deciding to take immediate clinical action;
- Involves detection, measurement, or recording of patient data and other functions of a patient monitoring device; or
- Transmits, stores, converts, or displays medical device data that are intended to be relied upon in deciding to take immediate clinical action or that are to be used for continuous monitoring by a health care professional, user, or the patient.¹⁸

For example, a telemedicine device used in conjunction with scheduled, routine patient care where immediate clinical action is not required could be regulated as a Class I MDDS device. To the extent that such a device uses two-way audio/video technology merely to capture and transmit patient-specific data, the device would maintain its Class I designation; however, where the manufacturer intends for the device to be used in active patient monitoring, a higher classification would be required.

The impact of the MDDS regulation is broad and affects organizations traditionally not regulated by FDA, including health care facilities that provide telemedicine services. **The FDA applies the MDDS regulation to anyone who manufactures an MDDS device, including health care facilities—e.g., a hospital, physician practice, or clinical—acting as manufacturers.**¹⁹ Determining whether a health care facility is considered a manufacturer can be tricky and depends on what the facility does with the product.

Facilities/Entities Regulated as a Device Manufacturer	Facilities/Entities NOT Regulated as a Device Manufacturer
<ul style="list-style-type: none"> • A facility/entity that purchases and reconfigures a product into an MDDS device. • A facility/entity that configures or modifies a purchased MDDS device in any way outside the scope of the product’s original specs, <i>even if</i> the modification is for the facility’s/entity’s clinical practice. • A facility/entity that develops its own software protocols or interfaces that have an intended use consistent with an MDDS device. • A facility/entity that develops, modifies, or creates a system from multiple components of devices and uses it clinically for functions covered by the MDDS classification. 	<ul style="list-style-type: none"> • A facility/entity that purchases an off-the-shelf MDDS device (hardware and/or software) and uses the device in accordance with the product’s labeling.

¹⁵ *Id.*
¹⁶ *Id.* at 8639.
¹⁷ *Id.* at 8649.
¹⁸ *Id.* at 8644.
¹⁹ *Id.* at 8645.

2. Mobile Medical Applications

After finalizing the MDDS regulation, the Agency expanded its efforts to other aspects of mobile health and telemedicine. In July 2011, the FDA published a draft guidance on the regulation of mobile medical applications,²⁰ in which the Agency described its current thinking on the regulation of software designed for a mobile platform and intended for use in the diagnosis, treatment, or prevention of disease. The guidance indicates FDA's belief that a mobile app may be subject to FDA regulation when used as an accessory to a medical device or when it transforms a mobile platform (e.g., a smartphone, tablet computer, etc.) into a regulated medical device.²¹

Types of regulated mobile apps include:

- Apps that **"connect to" one or more medical device(s)** for purposes of controlling the device(s) or displaying, storing, analyzing, or transmitting patient-specific medical device data;
- Apps that **transform the mobile platform** into a medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices; and
- Apps that **use algorithms that output a patient-specific result**, diagnosis, or treatment recommendation to be used in clinical practice.

For example, a smartphone app designed to allow a physician to perform a tele-ICU assessment might be regulated as a mobile medical app if it connects to a medical device (e.g., a stethoscope or blood pressure cuff), uses the smartphone's display screen or sensor (e.g., built-in accelerometer) for diagnostic or treatment purposes (e.g., for detecting heart sounds), or involves an algorithm that performs a patient-specific analysis (e.g., NIH stroke scale) to be used in clinical decision-making.

3. Clinical Decision Support Software

FDA also has begun to explore regulation of clinical decision support (CDS) software.²² Though not yet officially defined, the Agency has described CDS as:

Any software, whether designed as a mobile application, web-based service or desk top application, that uses an individual's information from various sources (electronically or manually entered) and that converts this information into new information that is intended to support a clinical decision.²³

²⁰ DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF: MOBILE MEDICAL APPLICATIONS (2011), available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf> [hereinafter MMA DRAFT GUIDANCE]; see also Draft Guidance for Industry and Food and Drug Administration Staff; Mobile Medical Applications; Availability, 76 Fed. Reg. 43,689 (July 21, 2011), available at <http://www.gpo.gov/fdsys/pkg/FR-2011-07-21/pdf/2011-18537.pdf>.

²¹ MMA DRAFT GUIDANCE, *supra* note 20, at 7.

²² As part of a public workshop on regulation of mobile apps, the FDA dedicated a half-day to discussion of CDS software. See U.S. Food & Drug Admin., *Public Workshop: Mobile Medical Applications Draft Guidance* (Sept. 13, 2011), <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm267821.htm>.

²³ Kristen Meier, Mathematical Statistician, Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin., *Standalone Clinical Decision Support (CDS) 2* (Sept. 13, 2011), available at <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM271894.pdf>.

FDA has given examples of CDS to include look-up databases, comparison algorithms, and simple calculators (e.g., software that produce an index or score based on known formulae). This expansive meaning suggests that FDA believes it can regulate any software that interprets *any* “actionable information” from virtually *any* source if the information or the result of the interpretation is intended to be used in the clinician’s decision-making process. Stakeholders in telemedicine will want to monitor whether the FDA continues down the path of regulating CDS software to include any type of algorithm or look-up table in the software for use in clinical decision-making.

III. INTOUCH HEALTH’S TELEMEDICINE SOLUTION

A. PRODUCT OVERVIEW

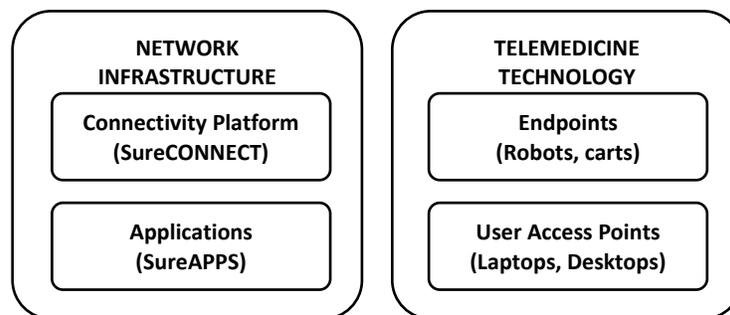
InTouch Health manufactures and distributes a range of FDA-cleared Remote Presence (RP) devices to provide care in a variety of health care settings,²⁴ including the emergency department, intensive care unit, patient wards, as well as operating and procedure rooms. As part of its telemedicine solution, InTouch Health offers:

- Equipment, connectivity, applications, service, support, and implementation;
- Program consultation and network strategy development; and
- End-to-end 24/7 support infrastructure.

Figure 1 provides an overview of the InTouch Telemedicine System. In general, the InTouch Telemedicine System involves:

- One or more RP devices or “Endpoints” that reside at the point of care;
- An RP ControlStation that resides at the clinician’s location;
- The InTouch® Telemedicine Platform that enables communication between the RP ControlStation and the various RP Endpoints; and
- A variety of software apps, called SureApps, that provide complementary utility during use of the RP devices.

Figure 1: InTouch Telemedicine System



²⁴ Letter from Bram D. Zuckerman, Dir., Division of Cardiovascular Devices, Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin., to Steve Sidwell, Dir. Of Regulatory Affairs & Quality Assurance, InTouch Health, Inc. (May 24, 2012), available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=39096>; Letter from Bram D. Zuckerman, Dir., Division of Cardiovascular Devices, Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin., to Bill Stout, Dir. of Operations, InTouch Technologies, Inc. (Apr. 11, 2008), available at http://www.accessdata.fda.gov/cdrh_docs/pdf7/K073710.pdf.

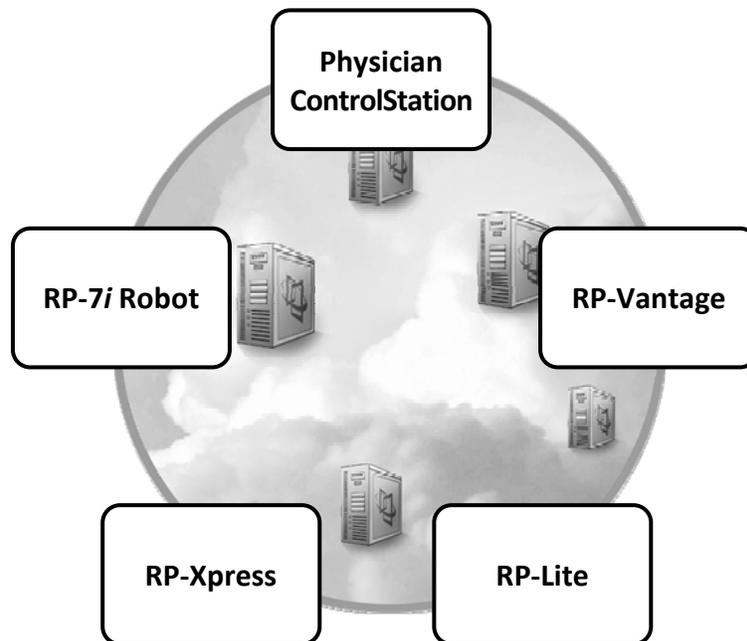
1. Telemedicine Technologies

The telemedicine technologies in the InTouch Telemedicine System consist of one or more RP Endpoints (e.g., RP-7 mobile robot) and a ControlStation (a desktop or laptop computer) that are typically linked via the Internet and a wireless network. InTouch Health markets (and continuously monitors as part of its service) an array of RP Endpoints, each with unique design features that facilitate its use in specific healthcare settings. The RP Endpoints currently on the market are:

- RP-7 and RP-7i: designed for use across multiple physician disciplines;
- RP-Vantage: designed to enable surgical telementoring and remote collaboration in operating and procedure rooms;
- RP-Lite: designed for use in a broad array of locations ranging from clinics, emergency rooms, rural hospitals, and long-term care communities, among others; and
- RP-Xpress: designed for use in ambulatory settings.

The RP Endpoints and ControlStation are equipped with cameras, displays, microphones, and speakers, allowing two-way audio/video communication. In the case of remote navigation of the mobile robot, the ControlStation may also be equipped with a joystick that the operator uses to control the RP Endpoints at the remote location. For example, with the RP-7 Endpoint, the user can move through a remote facility and engage in conversations as if physically present while seated at a ControlStation in a remote facility with broadband Internet access. Through use of these RP Endpoints, the health care facility can effectively extend the physician’s reach to manage patient care, thereby removing time and distance barriers.

Figure 2: InTouch Health’s Currently Marketed RP Endpoints



In addition to its core audio/video features, each RP Endpoint includes unique design features to facilitate the communication of patient data, such as an articulating boom arm with an attached pan-tilt-zoom camera (RP-Vantage), live telestration and collaboration tools (RP-Vantage),

stethoscope and privacy handset (RP-7 and RP-Lite), and on-board computer for data entry (RP-Lite).

2. Network Infrastructure

In addition to the RP Endpoints and ControlStation, the InTouch Telemedicine System includes the underlying network infrastructure that enables these system components to interface and enhances the communication experience. The SureConnect platform is a cloud-based telemedicine server infrastructure that provides secure connectivity between the RP Endpoints and the ControlStation. Built on top of the SureConnect platform is the ability to connect applications, which provide decision support, real-time collaboration and documentation tools that automate specific clinical workflows in a secure, HIPAA-compliant manner. Several of the SureApps include:

- StrokeRESPOND: Designed specifically to support the expert physician's acute stroke management workflow, this web-based application captures data elements relevant to the prescription of rt-PA, while also enabling the fastest possible clinical decision making.
- SureNotes: This web-based application enhances the telemedicine experience by providing a secure, easy-to-use software solution that automates existing hospital workflows for electronically documenting orders, notes, and charge data.
- MultiPRESENCE: This application allows a remote doctor to invite specialists into a telemedicine consult for collaboration, training or simply to improve the continuity of care.

These SureApps add design features to the InTouch Health Telemedicine Solution that facilitate the communication and storage of real-time audio/video as well as patient data for use by a healthcare professional in the delivery of care in a hospital or clinic environment.

B. REGULATORY SUMMARY OF INTOUCH HEALTH'S TELEMEDICINE SOLUTION

In 2008, the FDA cleared the InTouch Health RP system as a Class II medical device (more specifically, under the classification regulation for radiofrequency (RF) physiological signal transmitters and receivers).²⁵ The FDA generally defines this type of device as being "used to condition a physiological signal so that it can be transmitted via radiofrequency from one location to another, e.g., a central monitoring station."²⁶ Once received, this type of device reconditions the signal into its original format so that it can be displayed.²⁷

The Agency reviewed and cleared the RP system for the following uses:

- General Real-Time Communication Claims: Use in the transmission, receipt, and storage of real-time audio, video, and patient data;
- Auscultation Sound Claims: Use in the transmission of auscultation sounds via an electronic stethoscope;
- Other Biometric Signals Claims: Use in the transmission of vital signs and other biometric data from other 510(k)-cleared devices; and
- Acute Care Claims: Use in a hospital, clinic, or critical transport environment.

Note that the InTouch Health Telemedicine Solution is not a Class I MDDS device because it is intended for use in the active patient monitoring (e.g., pre-, peri-operative and post-surgical, cardiovascular, neurological, pre-natal, psychological, and critical care assessments and

²⁵ *Id.*

²⁶ 21 C.F.R. § 870.2910(a).

²⁷ *Id.*

examinations). The SureApps (e.g., StrokeRESPOND) software also performs CDS functionality that is beyond the scope of an MDDS device.

Other solutions that involve mobile apps or stand-alone CDS software would be regulated in a similar fashion as Class II devices requiring 510(k) submissions. For example, a mobile app that uses the audio/video features of a smartphone to facilitate diagnosis or treatment in an intensive care setting is not an MDDS device, but rather a Class II device. Similarly, a software app that analyzes patient-specific data (e.g., time from stroke onset) to inform a clinical decision (e.g., drug dosage) would be regulated as a CDS device, not an MDDS.

IV. CONCLUSION

The FDA regulates mobile health and telemedicine products depending on the level of risk and innovation associated with the device. Although some low risk and generally well-accepted mobile health and telemedicine technologies fall within the Class I domain (e.g., products that meet the definition of an MDDS device), the Agency has restricted the lowest regulatory oversight to those products that do not involve active patient monitoring. Instead, the FDA regulates active patient monitoring devices as either a Class II or III device, subject to premarket notification or approval requirements.

InTouch Health's Telemedicine Solution is cleared for use in active patient monitoring (e.g., pre-, peri-operative and post-surgical, cardiovascular, neurological, pre-natal, psychological, and critical care assessments and examinations). Therefore, InTouch Health's products fall outside of the MDDS Class I designation and are regulated as Class II medical devices.