5. 510(k) Summary

Name of 510(k) sponsor:	InTouch Health, Inc.
Address:	6330 Hollister Ave. Goleta, CA 93117
Contact information:	Steve Sidwell Director of Regulatory Affairs & Quality Assurance InTouch Health 6330 Hollister Ave. Goleta, CA 93117 Phone: 805 562 8686 (ext. 254) Fax: 805 562 8663
Date summary prepared:	October 11, 2012
Proprietary name of device:	Remote Presence System, Model RP-VITA™
Generic/classification name:	Transmitters and Receivers, Physiological Signal, Radiofrequency
Product code (classification):	21 C.F.R. § 870.2910, Product Code DRG; Class II

NOV 2 0 2012

Legally Marketed Predicate Device: InTouch Remote Presence System, Model RP-7i; K120895; May 24, 2012.

Device Description and Technological Characteristics:

The Remote Presence System, Model RP-VITA™ is a telecommunications platform that enables real-time videoconferencing and clinical communications, and provides a means for transmitting, receiving, and storing real-time audio and video, and patient data. The Remote Presence System, Model RP-VITA™ consists of a Control Station ("CS") (*i.e.*, desktop or laptop computer) and the RP-VITA™ end point that is controlled by an input device (*e.g.*, mouse or joystick) that the operator uses to control the movement of the RP-VITA™ from a remote location. The RP-VITA™ and CS are each equipped with various combinations of cameras, displays, microphones, and speakers, depending upon the specific CS used, which facilitate two-way audio-video communication. One accessory is a Class II, integrated electronic stethoscope, which is used for the same purpose for which it received 510(k) clearance. Communication between the CS and the RP-VITA™ end point is established via a wired broadband Internet connection or an 802.11 wireless broadband network connection.

Like the predicate device, the Remote Presence System, Model RP-VITA™ provides a real-time link between the patient and the healthcare professional. This link occurs over a wired or wireless broadband connection, and includes real-time audio and video to facilitate communication between the patient, patient-side healthcare professionals, and remote healthcare professionals. Also like the predicate, the Remote Presence System, Model RP-VITA™ provides connections for the transfer of data from 510(k)-cleared devices between the patient and the healthcare professional. Like the predicate device, these 510(k)-cleared devices are not controlled or manipulated through the Remote Presence System, Model RP-VITA™, and consequently, no additional risk is presented.

Expanding on the predicate device, the Remote Presence System, Model RP-VITA™ is available with an optional autonomous navigation system ("autonavigation"), providing the ability to autonomously navigate and position the RP-VITA™ end point to a pre-determined location. Developed in partnership with iRobot, the RP-VITA™ contains similar Auto Drive technology that is already being used successfully by the defense and

public safety communities (e.g., PackBot bomb disposal robots), as well as by consumers in household environments (e.g., Roomba vacuum cleaners). With a single click or tap, a bedside nurse or a remote clinician will be able to send the RP-VITA™ to the target destination. The RP-VITA™ features mapping and Obstacle Detection Obstacle Avoidance ("ODOA") technologies that support safe, fast, and highly flexible navigation in a clinical environment. As the technology name suggests, the ODOA system allows the RP-VITA™ to steer clear of obstacles in its path and maneuver around them. The RP-VITA's™ mapping technology creates and stores a digital map of a clinical environment that it can access in the future, labeling rooms, controlling device speed in certain areas, and marking areas where the RP-VITA™ should not travel. Risk analysis and the necessary verification and validation testing were performed to demonstrate that the design outputs of the RP-VITA™ meet the design input requirements.

Redundant safeguards are designed into the Remote Presence System, Model RP-VITA™ to address risks associated with both autonavigation and hardware and software improvements. The safety and effectiveness of these improvements were demonstrated by the verification and validation testing performed on the Remote Presence System, Model RP-VITA™. One article of the RP-VITA™ verification plan states that if a component critical to the ODOA system fails in autonavigation mode, the device will halt and not move as specified. Another article of the RP-VITA™ verification plan states that the device base has LED light strips that are capable of changing color to indicate various states of the device (e.g., autonavigation mode). An article of the RP-VITA™ validation plan states that when the device is in autonavigation mode, the device will slow down in narrow spaces (e.g. doorways less than three (3) feet) as well as slow down whenever un-mapped obstacles are detected nearby. The RP-VITA™ was tested successfully against these and other verification and validation articles to ensure the design outputs of the RP-VITA™ meet the design input requirements. In addition, the communication channel used by the electronic stethoscope was proven safe and effective by independent tests.

The performance data discussed in this 510(k) application demonstrate that the Remote Presence System, Model RP-VITA™ is as safe and effective as, and performs as well as or better than, the predicate device.

Intended Use:

The Remote Presence System, Model RP-VITA™ is a clinical communications tool that provides a means of transmitting, receiving, and storing real-time audio and video, and patient data. The Remote Presence System, Model RP-VITA™ may also be used in conjunction with 510(k)-cleared devices that transmit patient biometric data including vital signs information. The Remote Presence System, Model RP-VITA™ transmits and receives information over a high speed connection between patients, and health professionals. The Remote Presence System, Model RP-VITA™ can be used in communications for active patient monitoring in high acuity clinical environments where immediate clinical action may be required, e.g., pre-, peri-operative and post-surgical, cardiovascular, neurological, pre-natal, psychological and critical care assessments and examinations. Clinical judgment and experience are required to review and interpret the information transmitted.

Comparison with Predicate Device

A substantial equivalence table comparing the InTouch Remote Presence System, Model RP-VITA™ to the predicate device is provided below.

Table 5-1: Substantial Equivalence Comparison Table

	New Device	Predicate Device
510(k) #	To be assigned	K120895
Company	InTouch Health	InTouch Health
Name/Model #	Remote Presence System, Model RP-VITA™	Remote Presence System, Model RP-7i®
Indications for use	The Remote Presence System, Model RP-VITA™ is a clinical communications tool that provides a means of transmitting, receiving, and storing real-time audio and video, and patient data. The Remote Presence System, Model RP-VITA™ may also be used in conjunction with 510(k)-cleared devices that transmit patient biometric data, including vital signs information. The Remote Presence System, Model RP-VITA™ transmits and receives information over a high-speed connection between patients and health professionals. The Remote Presence System, RP-VITA™ can be used in communications for active patient monitoring in high acuity clinical environments where immediate clinical action may be required, e.g., pre-, peri-operative and post-surgical, cardiovascular, neurological, pre-natal, psychological, and critical care assessments and examinations. Clinical judgment and experience are required to review and interpret the information transmitted.	The Remote Presence System is a clinical communications tool that provides a means of transmitting, receiving, and storing real-time audio and video, and patient data. The Remote Presence System may also be used in conjunction with 510(k)-cleared devices that transmit patient biometric data, including vital signs information. The Remote Presence System transmits and receives information over a high-speed connection between patients, health professionals and critical transport teams. The Remote Presence System can be used in communications for active patient monitoring in high acuity clinical environments where immediate clinical action may be required, e.g., pre-, peri-operative and post-surgical, cardiovascular, neurological, pre-natal, psychological, and critical care assessments and examinations. Clinical judgment and experience are required to review and interpret the information transmitted.
Intended use	Telemedicine system	Telemedicine system
Intended users	Healthcare professional, inpatient, outpatient	Healthcare professional, inpatient, outpatient
Site of use	Hospital, clinic	Hospital, clinic, patient transport
Data collection software	Proprietary software	Proprietary software
Communication method with remote care management system	Broadband internet connection	Broadband Internet connection

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	New Device	Predicate Device
510(k) #	To be assigned	K120895
Company	InTouch Health	InTouch Health
Name/Model #	Remote Presence System, Model RP-VITA™	Remote Presence System, Model RP-7i®
Types of devices that can be interfaced (wired or wirelessly) to receiver hub	Electronic Stethoscope (K102893) and other cleared medical devices that transmit patient data.	Electronic Stethoscope (K034046) and other cleared medical devices that transmit patient data.
Implementation method of collecting data from device	External communication device	External communication device
Sensor software	Additional object detection and collision avoidance software	Object detection and collision avoidance software
Connectivity	Wired, wireless to hub	Wireless to hub
Communication method of hub with devices	RS-232, Serial communication, USB	RS-232, Serial communication, USB, Bluetooth®
Communications protocol	Proprietary or Session Initiation Protocol	Proprietary or Session Initiation Protocol
Wireless frequency	802.11 A, B, G or N (varies based on the customer)	802.11 A, B, or G (varies based on the customer)
Power source	Batteries with AC-DC battery chargers built in	Batteries with AC-DC battery chargers built in
Display	VGA Monitors on computers and end points	VGA Monitor on computers and end points
Video conferencing	2-way video conferencing via a broadband internet or cellular connection	2-way video conferencing via a broadband internet or cellular connection

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

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InTouch Health, Inc.
c/o Mr. Steve Sidwell
Director of Regulatory Affairs & Quality Assurance
6330 Hollister Avenue
Goleta, CA 93117

Re: K123229
Trade/Device Name: Remote Presence System, Model RP-VITA™
Regulatory Number: 21 CFR 870.2910
Regulation Name: Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulatory Class: II (two)
Product Code: DRG
Dated: October 12, 2012
Received: October 15, 2012

Dear Mr. Sidwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Applicant: InTouch Health, Inc.

510(k) Number: ~~Not assigned~~. K123229

Device Name: Remote Presence System, Model RP-VITA™

Indications for Use: The Remote Presence System, Model RP-VITA™ is a clinical communications tool that provides a means of transmitting, receiving, and storing real-time audio and video, and patient data. The Remote Presence System, Model RP-VITA™ may also be used in conjunction with 510(k)-cleared devices that transmit patient biometric data including vital signs information. The Remote Presence System, Model RP-VITA™ transmits and receives information over a high speed connection between patients, and health professionals. The Remote Presence System, Model RP-VITA™ can be used in communications for active patient monitoring in high acuity clinical environments where immediate clinical action may be required, e.g., pre-, peri-operative and post-surgical, cardiovascular, neurological, pre-natal, psychological and critical care assessments and examinations. Clinical judgment and experience are required to review and interpret the information transmitted.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

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