5. 510(k) Summary

MAY 2 4 2012

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:	March 22, 2012
Proprietary name of device:	Remote Presence System- RP-7i®, RP-B (a/k/a BoomBot and KSEA VisitOR1); RP-Lite®; KSEA VisitOR1 Cart; RP-Vantage®; and RP-Xpress™.
Generic/classification name:	Transmitters and Receivers, Physiological Signal, Radiofrequency
Product code (classification):	21 C.F.R. § 870.2910, Product Code DRG; Class II

Legally Marketed Predicate Device: InTouch Remote Presence Robotic System, Model RP-7; K073710; April 11, 2008

Device Description and Technological Characteristics:

The Remote Presence System 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 consists of a Control Station ("CS"), (*i.e.*, desktop or laptop computer) and an end point, which may be controlled by an input device (*i.e.*, mouse or joystick) that the operator uses to control the movement of the end point in the remote location (*e.g.*, RP-7® and RP-7i®), or manually located by the user (*e.g.*, RP-Lite®, KSEA VisitOR1 Cart, RP-Vantage®, or RP-Xpress™), or used in a restricted clinical environment, such as an operating room, where it is boom mounted (*e.g.*, BoomBot (aka RP-B and KSEA VisitOR1)). The end point and CS are each equipped with various combinations of cameras, displays, microphones and speakers, depending upon the specific device, which facilitate two-way audio-video communication. Optional accessories include Class II devices, including an integrated electronic stethoscope, which are used for the same purpose for which they received 510(k) clearance. Communication between the CS and the end-point is established via broadband Internet and an 802.11 wireless network or a broadband cellular connection.

Like the predicate device, the Remote Presence System 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 device, the Remote Presence System 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, and consequently, no additional risk is presented.

Expanding on the predicate device, the Remote Presence System introduces new cart-based and hand-held models, providing improved system flexibility by adapting to additional clinical environments (*e.g.*, operating rooms, emergency departments, intensive care units, patient transport, etc.).

Redundant safeguards are designed into the Remote Presence System to address risks associated with additional models, and hardware and software improvements. The effectiveness of these improvements was demonstrated by the validation testing performed on the system. The communication channel used by the electronic stethoscope was also proven effective by independent tests.

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

Intended Use:

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.

Comparison with Predicate Device

A substantial equivalence table comparing the InTouch Remote Presence System to the predicate device is provided below.

Table 5.1: Substantial Equivalence Comparison Table

	New Device	Predicate Device
510(k) #	To be assigned	K073710
Company	InTouch Health	InTouch Health
Name/Model #	Remote Presence System	Remote Presence Robotic System, Model RP-7
Indications for use	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.	The RP-7 is a communications tool that provides a means of transmitting, receiving, and storing real-time audio and video, and patient data. The RP-7 also can be used in conjunction with 510(k)-cleared devices that transmit patient biometric data, including vital signs information. The RP-7 transmits and receives information over a high speed connection between patients and health professional, and is intended to be used in a hospital or clinic environment. 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
Site of use	Hospital, clinic, patient transport	Hospital, clinic
Data collection software	Proprietary software	Proprietary software
Communication method with remote care management system	Wired or wireless broadband connection	Wired broadband connection

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	New Device	Predicate Device
510(k) #	To be assigned	K073710
Company	InTouch Health	InTouch Health
Name/Model #	Remote Presence System	Remote Presence Robotic System, Model RP-7
Types of devices that can be interfaced (wired or wirelessly) to receiver hub	Electronic Stethoscope (K034046) and other cleared medical devices that transmit patient data.	Electronic Stethoscope (K034046)
Implementation method of collecting data from device	External communication device	External communication device
Sensor software	Unchanged	Unchanged
Connectivity	Wired, wireless to hub	Wireless to hub
Communication method of hub with devices	RS-232, Serial communication, USB, Bluetooth®	RS-232, Serial communication
Communications protocol	Proprietary or Session Initiation Protocol	Proprietary
Wireless frequency	802.11 A, B, or G (varies based on the customer)	802.11 A, B, or G (varies based on the customer)
Power source	AC or 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
Video conferencing	2-way video conferencing via a broadband internet or cellular connection	2-way video conferencing via a broadband internet connection

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 24 2012

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

Re: K120895
Trade/Device Name: Remote Presence System RP-7i®, RP-B (a/k/a BoomBot and KSEAVisitOR1); RP-Lite®; KSEA VisitOR1 Cart; RPVantage®; and RP-Xpress™
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitters and Receivers,
Regulatory Class: Class II (two)
Product Codes: DRG
Dated: March 22, 2012
Received: March 26, 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.

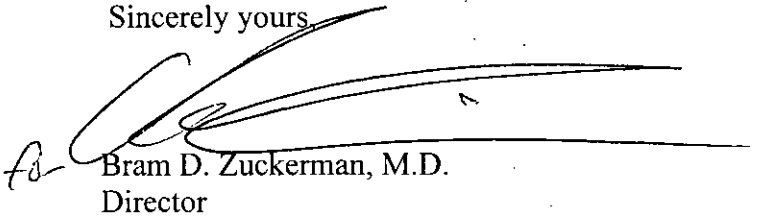
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

K120895

4. Indications for Use Statement

Applicant: InTouch Health, Inc.

510(k) Number: Not assigned.

Device Name: Remote Presence System

Indications for Use: 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.

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120895