March 25, 2019

InTouch Technologies, Inc., d.b.a. InTouch Health
% Ms. Karen Mullin
Manager Regulatory Affairs
7402 Hollister Avenue
GOLETA CA 93117

Re: K181716
Trade/Device Name: InTouch Thermal Camera™
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic System
Regulatory Class: Class I
Product Code: LHQ
Dated: February 19, 2019
Received: February 21, 2019

Dear Ms. Mullin:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181716

Device Name
InTouchThermal Camera

Indications for Use *(Describe)*
The InTouch Thermal Camera is intended to view, measure and record heat patterns and variations. It is intended for use as adjunctive diagnostic imaging for thermally significant indications stemming from heat emitted from the human body. The significance of these thermal patterns and variations is determined by professional investigation. This device is intended for use by qualified technical personnel trained in its use. Clinical judgment and experience are required to review and interpret the information transmitted.

The InTouch Thermal Camera is only for use in addition to other medical devices (i.e. Thermometer, Ultrasound, Mammography). It does not provide any absolute measurement of temperature and should not be used for sole screening or diagnosis for any disease or condition.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) Summary:

Name of 510(k) sponsor:	InTouch Technologies, Inc., d.b.a. InTouch Health
Address:	7402 Hollister Ave. Goleta, CA 93117
Contact information:	Karen Mullin Manager Regulatory Affairs InTouch Health 7402 Hollister Ave. Goleta, CA 93117 Phone: 805 562 8686 (ext. 370) Fax: 805 562 8663
Date summary prepared:	June 25, 2018 (updated February 18, 2019 and March 18, 2019)
Proprietary name of device:	InTouch Thermal Camera™
Generic/classification name:	System, Telethermographic (Adjunctive Use)
Product code (classification):	21 CFR § 884.2980, Product Code LHQ; Class I
Legally marketed predicate device:	Med-Hot Thermal Imaging System (Max 76) FLIR, K171928, December 8, 2017.

5.1 Device Description and Technological Characteristics:

The InTouch Thermal Camera™ is a hardware and software package that enables thermographic imagery and data during a real-time telemedicine consultation. The system includes a 320-pixel-wide thermal camera and a USB cable that allows connection of the camera to a Windows-based computer, which serves as the patient-side InTouch Health Telemedicine Device.

The InTouch Thermal Camera software consists of two components. The first is installed on a Windows-based system to serve as the InTouch Health Telemedicine Device. The second component is installed on a Windows or iOS-based system serving as the InTouch Health Provider Access device, enabling a healthcare professional access to the InTouch Health Telemedicine Device. The core software serves as a telecommunications platform that enables real-time videoconferencing and clinical communications, and provides a means of transmitting, receiving, and storing real-time audio and video data.

The InTouch Health Telemedicine System software provides a real-time link between the patient and the healthcare professional(s). The 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 professional(s). The InTouch Health software further provides an ability to toggle between an InTouch Health Telemedicine Device's optical camera and the InTouch Thermal Camera, or to view both simultaneously.

When utilizing the InTouch Thermal Camera, the clinician is provided with interface controls to allow a variety of options in the visualization of the thermal imagery.

The basic purpose of the InTouch Thermal Camera is to allow a physician to view the heat pattern of a patient, while engaged in a telemedicine consultation. When the InTouch Thermal Camera is engaged, the InTouch Health software provides the physician with a variety of controls for visualizing temperature patterns and temperature differences.

5.2 Indications for Use:
The InTouch Thermal Camera is intended to view, measure and record heat patterns and variations. It is intended for use as adjunctive diagnostic imaging for thermally significant indications stemming from heat emitted from the human body. The significance of these thermal patterns and variations is determined by professional investigation. This device is intended for use by qualified technical personnel trained in its use. Clinical judgment and experience are required to review and interpret the information transmitted.

The InTouch Thermal Camera is only for use in addition to other medical devices (i.e. Thermometer, Ultrasound, Mammography). It does not provide any absolute measurement of temperature and should not be used for sole screening or diagnosis for any disease or condition.

WARNING:
The InTouch Thermal Camera should not be used as the sole device to diagnose or screen for breast cancer or any other condition. The InTouch Thermal Camera should not be used in place of mammography and is only for use in addition to other diagnostic or screening devices. Incorrect use of the InTouch Thermal Camera carries the risks of a delayed or missed diagnosis, or unnecessary additional tests.

5.3 Comparison with Predicate Device:

A substantial equivalence table comparing the InTouch Thermal Camera (proposed device) to the predicate device is provided in Table 5-1 below.

Table 5-1: Comparison of the Proposed Device to the Predicate Device

Product	InTouch Thermal Camera (proposed device)	Med-Hot Thermal Imaging System (Max 76) (predicate device)
Manufacturer	InTouch Health	Med-Hot Thermal Imaging, Inc.
Indications for Use	The InTouch Thermal Camera is intended to view, measure and record heat patterns and variations. It is intended for use as adjunctive diagnostic imaging for thermally significant indications stemming from heat emitted from the human body. The significance of these thermal patterns and variations is determined by professional investigation. This device is intended for use by qualified technical personnel trained in its use. Clinical judgment and experience are required to review and interpret the information transmitted.	The Med-Hot Thermal Imaging Systems are intended to review, measure and record skin temperature patterns and variations emitted from the human body. They are intended for use as adjunctive diagnostic imaging for thermally significant indications in the regions of the head and neck, breast, chest, abdomen, back and extremities. The significance of the value of these thermal patterns is determined by professional investigation. This device is intended for use by qualified technical personnel trained in its use.
Device Class	I	I
510(k) Clearance	K181716	K171928
Predicate	K171928	K063047
Imaging		
Detector Type	Uncooled VOx microbolometer	Uncooled VOx microbolometer
Array Format	320 x 256	320 x 240
Pixel Pitch	12 µm	25 um (Detector Pitch)
Spectral Range	Longwave infrared; 7.5 µm to 13.5 µm	Longwave infrared; 7.5 um to 13 um
Frame Rate	60 Hz	60 Hz
Thermal Sensitivity	< 60 mK (Consumer grade)	< 50 mK
Accuracy	+/- 1.1 °C (for temperature difference)	± 2 C or ± 2 % of Reading

Table 5-1: Comparison of the Proposed Device to the Predicate Device, cont.		
Optics		
Array Format	320 x 256 with 24° field of view	320 x 240
Electrical		
Video Channels	USB-2	Gig E
Control Channels	USB	Gig E
Input Voltage	3.3 VDC	110/220VAC
Power Dissipation	Varies by configuration; as low as 500 mW	Not stated
Environmental		
Operating Temperature Range	-40°C to 80°C	-40 °C to 150 °C (40 °F to 302 °F)
Non-operating Temperature Range	-50°C to 105°C	-40 °C to 150 °C (40 °F to 302 °F)

5.4 Non-Clinical Testing:

- IEC 60601-1-2:2014 4th Edition Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 62366:2007 Ed. 1+A1 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety & Essential Performance
- IEC 60601-1-6:2010 Ed. 3+A1 Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
- IEC 60601-1:2005 Ed. 3+A1 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- AAMI ES60601-1:2005+A1 Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance
- Software verification and validation according to FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

5.4.1 Summary of Accuracy:

The InTouch Thermal Camera temperature difference accuracy was calculated and verified to be +/- 1.1 °C at 99% confidence with a measurement bias within +/-0.1 °C. To determine these values, data was collected over multiple cameras, multiple users, and multiple temperatures ranging from 22-48 °C. Traceable certified reference black body

calibrators and thermocouples were employed in order to establish the temperature difference accuracy and bias, and a Gage Repeatability & Reproducibility was run to assess the variation of the measurement system. The root sum of squares method was employed to compute the overall uncertainty of the system at the given confidence interval.

5.5 Clinical Studies:
No clinical studies were conducted.

5.6 Conclusion:
Based on the technology characteristics and non-clinical testing, it is the conclusion of InTouch Health that the InTouch Thermal Camera is substantially equivalent to the predicate device and raises no new issues of safety.