April 12, 2022

USA Therm, Inc.
% Mary Vater
510(k) Consultant
Medical Device Academy
345 Lincoln Hill Road
SHREWSBURY VT 05738

Re: K213650
Trade/Device Name: ThermPix Thermovisual Camera
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic system
Regulatory Class: Class I, reserved
Product Code: LHQ
Dated: March 3, 2022
Received: March 3, 2022

Dear Mary Vater:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213650

Device Name
ThermPix Thermovisual Camera

Indications for Use *(Describe)*
The ThermPix Thermovisual 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. Clinical judgement and experience are required to review and interpret the information transmitted.
The ThermPix Thermovisual Camera is only for use in addition to other diagnostic medical devices. It does not provide any absolute measurement of temperature and should not be used for sole screening or diagnosis for any disease or condition. The system is not intended to be used as a thermometry device.

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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510(k) SUMMARY - K213650

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

USA Therm, Inc.
21550 Biscayne Boulevard, Suite 133
Aventura, Florida 33180
Tel: +1.844.998.4376
Fax:

Contact Person: Ariel Soffer, MD, CEO
Date Prepared: November 18, 2021

II. DEVICE

Name of Device:	ThermPix Thermovisual Camera
Classification Name:	Telethermographic System
Regulation:	21 CFR §884.2980
Regulatory Class:	Class I
Product Classification Code:	LHQ

III. PREDICATE DEVICE

Predicate Manufacturer:	InTouch Health
Predicate Trade Name:	InTouch Thermal Camera™
Predicate 510(k):	K181716

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The ThermPix Thermovisual Camera is a Telethermographic system which consists of infrared and visual cameras and a touch-screen display. It is a non-contact, non-invasive, and non-radiating infrared system capable of imaging and storing thermal patterns generated by the human body. These images along with other patient-specific data are uploaded via Wifi to the ThermPix Cloud, a secure repository where clinicians can access and augment data from a 3rd party device or computer.

It employs passive infrared emission sensing technology to capture the thermal data and uses proprietary software to display the temperature distribution pattern as an image. It is suitable for imaging adult human targets and can be used in hospitals, acute and sub-acute healthcare settings, clinics, and any environment where healthcare is provided by a healthcare professional.

V. INDICATIONS FOR USE

The ThermPix Thermovisual 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. Clinical judgement and experience are required to review and interpret the information transmitted.

The ThermPix Thermovisual Camera is only for use in addition to other diagnostic medical devices. It does not provide any absolute measurement of temperature and should not be used for sole screening or diagnosis for any disease or condition. The system is not intended to be used as a thermometry device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

	ThermPix Thermovisual Camera	InTouch Thermal Camera (K181716)	Comments on Substantial Equivalence
Indications for Use	The ThermPix Thermovisual 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. Clinical judgement and experience are required to review and interpret the information transmitted. The ThermPix Thermovisual Camera is only for use in addition to other diagnostic medical devices. It does not provide any absolute measurement of temperature and should not be used for sole screening or diagnosis for any disease or condition. The system is not intended to be used as a thermometry device.	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.	Both devices are indicated to view, measure, and record heat patterns and variations as an adjunctive diagnostic imaging device for thermally significant indications stemming from heat emitted form the human body. The significance of these thermal patterns and variations is determined by professional investigation. Both devices also indicate that they are not intended for absolute temperature measurement or sole screening.
Intended User	Healthcare Professionals	Healthcare Professionals	Identical
Environment of Use	Clinical Environment	Clinical Environment	Identical
Imaging			
Detector Type	Uncooled VOx microbolometer	Uncooled VOx microbolometer	Identical
Pixel Pitch	12 µm	12 µm	Identical

Spectral Range	Longwave infrared; 7.8 µm to 14 µm	Longwave infrared; 7.5 µm to 13.5 µm	Substantially Equivalent
Frame Rate	9 Hz and 27 Hz	60 Hz	Substantially Equivalent
Thermal Sensitivity	65 mK (typical)	< 60 mK (Consumer grade)	Substantially Equivalent
Accuracy	+/- 1°C (for temperature difference)	+/- 1.1 °C (for temperature difference)	Substantially Equivalent
Optics			
Array Format	320 x 240 with 56° (H) and 42° (V) field of view	320 x 256 with 24° field of view	The subject device has a wider field of view that allows the user to be closer to areas of interest than the predicate, otherwise no practical difference
Electrical			
Video Channels	USB-2	USB-2	Identical
Control Channels	USB	USB	Identical
Input Voltage	3.3 VDC to 5 VDC (5V used)	3.3 VDC	Results in no practical performance difference
Power Dissipation	300 mW	Varies by configuration; as low as 500 mW	Lower power consumption than predicate is of no practical difference
Environmental			
Operating Temperature Range	-10°C to +60°C (15°C to 24°C recommended for best results)	-40°C to 80°C	Differences due to use of Lithium polymer rechargeable battery that looses capacity at low temperatures. Of no practical consequence because intended use location is in a doctor's office or hospital.
Non-Operating Temperature Range	-40°C to 60°C	-50°C to 105°C	
Performance Testing			
Temperature Difference Accuracy	The ThermPix Thermovisual Camera temperature difference accuracy was calculated and verified to be +/- 0.68°C at 95% confidence (1.02°C at 99%) with a	The InTouch Thermal Camera temperature difference accuracy was calculated and verified to be +/- 1.1 °C at 99% confidence with a measurement bias within	Near identical: - The accuracy of the subject device is slightly better than predicate

	measurement bias within +/-0.1 °C. To determine these values, data was collected over multiple cameras, multiple users, and multiple temperatures ranging from 20-40 °C. A traceable certified reference black body calibrator 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.	+/-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.	but the difference is within the +/-0.1 certainty interval. - Subject device assessment was in the range between 10-40°C as this is deemed closer to the temperatures of human skin than the predicate's 22-48°C.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

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 60601-1:2005 Ed. 3+A1 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- Software verification and validation according to IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes and FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Summary of Accuracy

Relative Temperature Difference (thermal sensitivity)

The ability of the ThermPix Thermovisual System to enable users to distinguish temperature differences of 1°C with a thermal image was tested using image data collected from 2 cameras at temperatures ranging from 20°C to 40°C in increments of 2°C. Results indicate that with 99% confidence temperature differences in 1°C or more are discernible by a trained user.

The results indicate that the device performance is comparable to that of the proposed 510(k) predicate device K181716 with a reported error of 1.1°C at the 99% confidence level.

Human Clinical Performance Testing

Clinical testing was not required to demonstrate the safety and effectiveness of the device.

VIII. CONCLUSIONS

Based on the technology characteristics and non-clinical testing, it is the conclusion of USA Therm, Inc. that the ThermPix Thermovisual Camera is substantially equivalent to the predicate device and raises no new issues of safety.