September 14, 2023

USA Therm, Inc.
% Mary Vater
510(k) Consultant
Medical Device Academy
345 Lincoln Hill Rd.
SHREWSBURY VT 05387

Re: K232462
Trade/Device Name: ThermPix Thermovisual Camera
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic system
Regulatory Class: Class II
Product Code: LHQ
Dated: August 14, 2023
Received: August 15, 2023

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,

Yanna S. Kang -S

Yanna Kang
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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.

Submission Number *(if known)*

K232462

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY K232462

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.
3100 Ray Ferrero Jr. Blvd, 5th Floor
Fort Lauderdale FL 33314 United States
Tel: +1.844.998.4376
Contact Person: Mr. Eric Heil
Date Prepared: August 15, 2023

II. DEVICE

Device Trade Name:	ThermPix Thermovisual Camera
Classification Name:	Telethermographic System
Regulation:	21 CFR §884.2980
Regulatory Class:	Class II
Device Panel:	Radiology
Product Classification Code:	LHQ

III. PREDICATE DEVICE

Predicate Manufacturer:	USA Therm, Inc.
Predicate Trade Name:	ThermPix Thermovisual Camera
Predicate 510(k):	K213650

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The ThermPix Thermovisual Camera is a Telethermographic system which consists of an infrared camera embedded in a Tablet case and a Commercial Off the Shelf Tablet (WIFI only). 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 WITH PREDICATE

	Predicate Device: ThermPix Thermovisual Camera	Subject Device: ThermPix Thermovisual Camera	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 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.	Identical

	The system is not intended to be used as a thermometry device.	The system is not intended to be used as a thermometry device.	
Intended User	Healthcare Professionals	Healthcare Professionals	Identical
Environment of Use	Clinical Environment	Clinical Environment	Identical
Device Components	• Camera Swivel Drum • Micro SD Card • Infrared Camera • Visual Camera • Touch Screen and Screen Driver • Computing PCB • Lithium Polymer Battery • Anti-Bacterial Case	• Commercial Off the Shelf Tablet (WIFI Only). Testing to be performed on Samsung Galaxy S6 Lite WIFI Only (Model SM-P610NZAAXAR) • SEEK Infrared camera • Molded Tablet case • USB C Hub • Pen Stylus	The device components are the key differences between device generations. The changes to design do not impact the device's performance capabilities or the user's interactions with the device.
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; 7.8 µm to 14 µm	Identical
Frame Rate	9 Hz and 27 Hz	9 Hz	Substantially Equivalent
Thermal Sensitivity	65 mK (typical)	65 mK (typical)	Identical
Accuracy	+/- 1°C (for temperature difference)	+/- 1°C (for temperature difference)	Identical
Optics			
Array Format	320 x 240 with 56° (H) and 42° (V) field of view	320 x 240 with 56° (H) and 42° (V) field of view	Identical
Electrical			
Video Channels	USB-2	USB-2	Identical
Control Channels	USB	USB	Identical
Input Voltage	3.3 VDC to 5 VDC (5V used)	5VDC	Results in no practical performance difference
Environmental			
Operating Temperature Range	-10°C to +60°C (15°C to 24°C recommended for best results)	-10°C to +60°C (15°C to 24°C recommended for best results)	Identical
Non-Operating Temperature Range	-40°C to 60°C	--40°C to 60°C	
Performance Testing			
Temperature Difference Accuracy	The ThermPix Thermovisual Camera temperature difference	The subject device was validated using identical methods.	Identical

	accuracy was calculated and verified to be +/- 0.68°C at 95% confidence (1.02°C at 99%) 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 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.		

VII. PERFORMANCE DATA

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

Electrical safety and electromagnetic compatibility (EMC)

The subject device passed equivalent electrical safety and EMC testing in accordance with:

- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION

Software Verification and Validation Testing

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

Performance Validation Testing

The subject device was validated using identical methods to the predicate device. 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.

VIII. CONCLUSIONS

Based on the technological 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.