December 8, 2017

Med-Hot Thermal Imaging, Inc.
% E. J. Smith
Consultant
Smith Associates
1468 Harwell Avenue
CROFTON MD 21114

Re: K171928
Trade/Device Name: Med-Hot Thermal Imaging Systems
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic System
Regulatory Class: I
Product Code: LHQ
Dated: October 28, 2017
Received: November 2, 2017

Dear E. J. Smith:

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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Michael D. O'Hara For

Robert Ochs, 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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K171928

Device Name
Med-Hot Thermal Imaging Systems

Indications for Use *(Describe)*
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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Sponsor:	Med-Hot Thermal Imaging, Inc.
Company Address:	5120 S. Florida Ave., Suite 301
	Lakeland, FL 33813
Telephone:	863-646-1599
Fax:	863-646-1544
Contact Person:	Carol Chandler

Summary Preparation Date: December 6, 2017

Device Name:

Trade Name:	Med-Hot Thermal Imaging Systems
Common/Usual Name:	System, Telethermographic (Adjunctive Use)
Classification Name:	System, Telethermographic (Adjunctive Use)
Regulation Number:	21 CFR 884.2980
Device Class:	Class I

Predicate Device:

Manufacturer	Product Name	510(k) Number
Med-Hot Thermal Imaging, Inc.	MTI 2000	K063047

Device Description:

The Med-Hot Thermal Imaging Systems are non-contact infrared imaging devices, with all functions controlled at the computer screen. TotalVision is a patented, clinical personnel-friendly software application, validated in the field. The system is delivered with a computer including installed and tested software.

The Med-Hot Thermal Imaging camera is suitable for high quality imaging of the human body:

- The resolution (320 X 240 / 640 X 480) provides adequate detail to detect and visualize minute thermal details
- Microbolometer technology provides low power consumption and high temperature reliability
- 50-60 Hz image frequency provides real-time image viewing and capture with no loss of detail due to movement.
- Automatic focus option to provide privacy imaging, a comfort feature for both client and

user

- Gigabit Ethernet interface-fastest industry standard for data transfer of data dense files
- Factory calibration – temperature conversion files reside in the camera firmware, not in the user's computer, providing reliable, enhanced accuracy. See explanation below.
- 25 degree standard lens provides the most practical field of view in a clinical setting with limited space.

The TotalVision Capture Software allows for incoming image data from the camera head and configures that data in a form that can be displayed on the computer screen. This display will include an image of the scene within the camera's field of view allowing the user to visualize thermal patterns or analyze the image in terms relative temperature values. The software makes no determination regarding what the thermal patterns or relative temperature values mean. It will be left to the user to infer areas of interest based on his/her visual interpretation of those patterns or values.

The new device consists of:

1. Infrared Camera
    - MAX 076 320 x 240 array detector
    - MAX 307 640 x 480 array detector
2. TotalVision Software
3. Laptop or desktop computer

Indications for Use:

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.

Predicate Device Comparison:

Synopsis of the comparison analysis:

- Med-Hot Thermal Imaging Systems and the predicate device (MTI 2000) are intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, screening of differences in skin surface temperature changes.
- Both view live imagery from the camera, record snap shots to disk, include post-processing of fast thermal events, provide analysis by region of interest (spot, line, square) and save the information in a file organizer.
- The Med-Hot TotalVision Capture software is an evolution of the original Med-Hot software program included in K063047. Improvements and new features added were based on user-driven needs and requests over the years.

Comparison of Intended Use and Principle of Operation:

As thermal sensors, the principle operation of all thermal imaging or infrared cameras is inherently the same, regardless of technical specifications or applications. They capture and record objects within the camera view for evaluation of thermal variations.

For clinical or medical application, the information from and infrared device is strictly limited to thermal findings. The location of these findings on the body, combined with intensity and distribution of thermal patterns may lead the reader/observer to intentionally or incidentally make a thermal correlation with the expected or abnormal patterns to the anatomy in that region of the body.

The Med-Hot Thermal Imaging Systems is substantially equivalent in intended use, principle of operation and similar software features to the FDA cleared Med-Hot Thermal Imaging, Inc. MTI2000.

Non-Clinical Performance Testing:

- ISO 14971, Medical devices - application of risk management to medical Devices
- IEC 60068-2-27 Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock
- IEC 60068-2-6 Environmental testing - Part 2-6: Tests - Test Fc: Vibration
- IEC 60529 Degrees of protection provided by enclosures (IP Code)
- EN 61000-6-3 Electromagnetic compatibility (EMC). Generic standards. Emission standard for residential, commercial and light-industrial environments
- EN 61000-6-2 Electromagnetic compatibility (EMC). Generic standards. Immunity for industrial environments
- EN 60950 Information technology equipment - Safety - Part 1: General requirements
- 47 CFR Part 15 - RADIO FREQUENCY DEVICES
- Software Verification and validation according to FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Clinical Studies:

No clinical studies were conducted.

Conclusion:

Based upon the technology characteristics and safety and performance testing, it is the conclusion of Med-Hot Thermal Imaging Inc., that the Med-Hot Thermal Imaging Systems are as safe and effective as the predicate devices and raises no new issues of safety and effectiveness.