Thermidas Americas, Inc.
% Samantha L. Prokop, Esq.
Attorney
Gunster, Yoakley & Stewart, P.A.
225 Water Street, Suite 1750
JACKSONVILLE FL 32202

January 6, 2021

Re: K200999
Trade/Device Name: Thermidas IR System (ThIR-A615)
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic System
Regulatory Class: Class I, reserved
Product Code: LHQ
Dated: November 24, 2020
Received: November 25, 2020

Dear Samantha Prokop:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200999

Device Name
Thermidas IR System (ThIR-A615)

Indications for Use *(Describe)*
The Thermidas IR System is for adjunctive use in addition to other clinical diagnostic procedures for diagnostic imaging for thermally significant indications of all skin regions of the human body. The system is for reviewing and reporting of temperature patterns and changes. The significance of the value of these thermal patterns is determined by professional investigation. The system is not intended for absolute temperature measurements. The Thermidas IR system is intended for use by trained technical personnel.

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
K200999

Submitter: Thermidas Americas, Inc.
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Contact Person: Karo Kujanpaa
Date Prepared: 12.11.2020

Trade Name: Thermidas IR System (ThIR-A615)
Common Name: System, Telethermographic (Adjunctive Use)
Product Code/Primary: LHQ
Regulation: 21 CFR 884.2980
Classification Name and Class: System, Telethermographic (Adjunctive Use), Class I
Reason: New Device

Predicate Device

Manufacturer: Med-Hot Thermal Imaging, Inc.
Trade/Proprietary/Model Name: Med-Hot Thermal Imaging Systems
510(k) Number: K171928

Background

The ability to use Infrared technology to measure temperature variations and patterns of the body's service is commonplace technology.

Thermal imaging devices are non-invasive systems that do not touch the patient's body. The devices use infrared radiation technology to detect, measure, and quantify patterns and variations in skin temperature. The data is converted via software using algorithmic derivatives to an image on a computer screen.

Thermal imaging is a technique that can be employed by trained medical professionals and used as an adjunctive diagnostic screening tool (in conjunction with medical examination and other diagnostic tests) to detect skin temperature variation.

Device Description

The Thermidas IR System consists of an off-the-shelf thermal imaging camera, a mount for the camera and a Windows workstation running the Thermidas Imager software. The Thermidas IR System is a non-invasive medical device which uses infrared radiation naturally emitted by the patient, which senses variations in temperature. The captured data is processed by software producing a quantitative image on the computer screen. The medical professional can use the image to review, analyze, investigate, and quantify the temperature of the objects that are

imaged.

Indications for Use

The Thermidas IR System is for adjunctive use in addition to other clinical diagnostic procedures for diagnostic imaging for thermally significant indications of all skin regions of the human body. The system is for reviewing and reporting of temperature patterns and changes. The significance of the value of these thermal patterns is determined by professional investigation. The system is not intended for absolute temperature measurements. The Thermidas IR system is intended for use by trained technical personnel.

Predicate Device Comparison

Med-Hot Thermal Imaging System	**Thermidas IR-System**
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 personnelfriendly software application, validated in the field. The system is delivered with a computer including installed and tested software.	Thermidas IR System consists of a mobile workstation, an off-the-shelf IR imaging camera, a camera arm, a camera mount providing adjustable fixing point for the camera, a Windows workstation running the Thermidas Imager software and a display, a keyboard and a mouse.
The Med-Hot Thermal Imaging camera is suitable for high quality imaging of the human body:	Thermidas IR-System provides the following features:
• The resolution (320 X 240 / 640 X 480) provides adequate detail to detect and visualize minute thermal details	• CE-marked setup supports 640x480 resolution. However, technically the system can also support the 320x240 resolution. In clinical work the higher resolution is more feasible.
• Microbolometer technology provides low power consumption and high temperature reliability	• 640 x 480 pixel microbolometer that detects temperature differences as small as 50 mK, for accuracy at longer distances.
•50-60 Hz image frequency provides realtime image viewing and capture with no loss of detail due to movement.	• Stream full-frame 16-bit images at 50 Hz, or in windowed mode as high as 200 Hz, for high-speed processes.
•Automatic focus option to provide privacy imaging, a comfort feature for both client and user	• Automatic and manual focus
• Gigabit Ethernet interface-fastest industry standard for data transfer of data dense files	• Gigabit Ethernet
• Factory calibration – temperature conversion files reside in the camera	• System calibration that is done at the factory during manufacture

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.	• Lens: 25 degree
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.	Thermidas Imager software is supplied with a database where user can add new patient data, and access and modify stored data. The images are displayed in real time on the screen of the computer during the measurement session. The acquired IR images and IR video clips are stored in the database along with patient data and identifying information such as date of acquisition. The images are stored as thermographic maps that visualize the patterns and variations of the relative skin temperatures of the patients. The software provides means for viewing the IR images stored in the database and analyzing the data. The software allows the user to change the color scales and visualization of the colors to compare previously recorded images. The software also provides tool for the user to e.g. compare variations of relative temperature values between two or more regions of interest on the images. The data analysis is based on the professional skills and experience of the trained user. The decision making is not based on the software itself. Thermidas Imager software supports: • Patient records (add and modify) • Image capture (still images and video (length: 3,5 or 10 sec.)) • Visualization of acquired and stored images • Addition of text comments as annotations

	• Placement and modification of Regions of Interest including display of statistical information (min value, max value, average value, radius) • Storage of images in png and jpg file formats • Reporting tool to pdf file format
The new device consists of:	The device consists of:
1. Infrared Camera ► MAX 076 320 x 240 array detector ► MAX 307 640 x 480 array detector	1. Infrared Camera ► ThIR-A615 640x480 array detector (certified) ► ThIR-A615 320 x 480 array detector (*non-certified*)
2. TotalVision Software	2. Thermidas Imager software
3. Laptop or desktop computer	3. Camera arms, Medical PC and monitor in a battery-operated mobile workstation 4. Remote data analysis using a laptop PC
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.	The Thermidas IR System is for adjunctive use in addition to other clinical diagnostic procedures for diagnostic imaging for thermally significant indications of all skin regions of the human body. The system is for reviewing and reporting of temperature patterns and changes. The significance of the value of these thermal patterns is determined by professional investigation. The system is not intended for absolute temperature measurements. The Thermidas IR system is intended for use by trained technical personnel.

Comparison of Intended Use and Principle of Operation:

Thermal sensor technology is essentially the same among various products regardless of technical specifications or applications used. Thermal imaging captures and records objects within the view of the camera using the captured object's naturally emitted infrared radiation.

The devices use infrared radiation technology to detect, measure, and quantify patterns and variations in skin temperature. The data is converted via software using algorithmic derivatives to an image on a computer screen.

As used in the medical field the information from infrared devices are strictly limited to thermal findings. The medical professional/reviewer may use information gathered from the devices and subsequent image such as location of findings, distribution of thermal patterns, and intensity to

make a thermal correlation with expected or abnormal patterns for the imaged region of the body.

The Thermidas IR System is substantially equivalent to the intended use, principle operation and similar software features the already FDA-cleared Red-Hot Thermal Imaging Systems (K171928). Please refer to 510(k) summary, premarket notification and additional information for the Med-Hot Thermal Imaging Systems predicate device as set forth in Section 12 of this application.

Non-Clinical Performance Testing

EN ISO 13485:2016

EN IS 14971:2012

IEC 62304:2015 (Ed 1.1)

EN 62366-1:2015

EN 60601-1:2006+A1:2013

EN 606001-1-2:2015

IEC 60601-1-2:2014

ANSI/AAMI ES60601-1:2005/(R)2012

Directive 93/42/EEC on Medical Devices, Annex II for infrared imaging devices for medical diagnostic purposes.

Clinical Performance Testing

Clinical studies are not required for this Class I device and have not been performed.

Compatibility

The Thermidas IR System is compatible with Flir, Inc.'s A615 infrared camera.

Conclusion

Based on the foregoing, the Thermidas IR System is substantially equivalent in terms of technology, safety, performance testing, and indications for use as the predicate devices Med-Hot Thermal Imaging Systems and is as safe and effective as the predicate device, raising no new issues of safety or effectiveness.