DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Alfa Thermodiagnostics, Inc.
% Mr. John Smith
Regulatory Counsel
555 13th Street, N.W.
WASHINGTON DC 20004

April 10, 2015

Re: K150457
Trade/Device Name: AlfaSight 9000 Thermographic System
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic system
Regulatory Class: I
Product Code: LHQ
Dated: February 20, 2015
Received: February 20, 2015

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting 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 below.

510(k) Number *(if known)*
K150457

Device Name
AlfaSight 9000 Thermographic System

Indications for Use *(Describe)*
The AlfaSight 9000 is intended for the adjunct diagnosis of: 1) abnormalities of the female breast; 2) peripheral vascular disease; 3) musculoskeletal disorders; 4) extracranial cerebral and facial vascular disease; 5) abnormalities of the thyroid gland; and 6) various neoplastic and inflammatory conditions.

The AlfaSight 9000 is not intended to serve as a sole diagnostic screening procedure.

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.

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510(k) SUMMARY

DATE	February 20, 2015
SUBMITTER	Alfa Thermodiagnostics, Inc. 9057 Soquel Drive, Suite B-AA Aptos, CA 95003 Tel: (831) 901-9248 Fax: (831) 685-1128 Email: drbeilin@alfathermo.com
CONTACT PERSON	Daniel Beilin, O.M.D., Alfa Thermodiagnostics, Inc 9057 Soquel Drive, B-AA Aptos, CA. 95003 Tel: (831) 901-9248 Fax: (831) 685-1128 Email: drbeilin@alfathermo.com
DEVICE NAME	AlfaSight 9000 Thermographic System
Classification:	Class I
Common Name	Telethermographic system
Classification	21 C.F.R. § 884.2980 (adjunctive use)
Product Code	LHQ
Review Panel	Obstetrics/Gynecology
PREDICATE DEVICE	Eidam's CRT 2000 (K971956)
INTENDED USE	The AlfaSight 9000 is intended for the adjunct diagnosis of: 1) abnormalities of the female breast; 2) peripheral vascular disease; 3) musculoskeletal disorders; 4) extracranial cerebral and facial vascular disease; 5) abnormalities of the thyroid gland; and 6) various neoplastic and inflammatory conditions. The AlfaSight 9000 is not intended to serve as a sole diagnostic screening procedure.

DEVICE DESCRIPTION

The AlfaSight 9000 system is a non-invasive, handheld and battery-operated adjunctive diagnostic device that measures and records skin surface temperatures. The system is intended for use as an adjunct to other clinical diagnostic procedures to quantify relative skin surface temperatures. It is not intended as a sole diagnostic device and does not replace or substitute any clinical test or device such as X-Ray, CT scans, mammography or other similar equipment. The system is for prescription-only use by licensed medical practitioners for use in hospitals, sub-acute healthcare settings, and private clinics.

The AlfaSight 9000 system consists of: 1) a handheld probe, 2) an off-the-shelf computer 3) a standard USB charging cable and 4) biocompatible sheaths. The single use sheath is placed over the handheld probe covering the entire probe, three capacitive sensitive pins sense contact of the skin through the sheath to start the

temperature measurement. Temperature samples are then sent from the handheld probe to the computer wirelessly using Bluetooth technology and are represented in a graphical display on the computer. Samples are organized into specified regions of the body as they are sampled in a fixed order as directed by the software.

SUBSTANTIAL EQUIVALENCE

A comparison of the AlfaSight 9000 System's indications for use, technological characteristics, and principles of operation with the predicate device indicates that the AlfaSight 9000 system is substantially equivalent to the FDA-cleared CRT 2000 thermographic device (K971956).

The AlfaSight 9000, like the predicate device CRT-2000, is intended as an adjunct to other clinical diagnostic procedures. The indications for use are identical to the indications for the predicate CRT-2000 device.

The AlfaSight 9000 system differs from its predicate, the CRT-2000, in that it measures the skin temperature (through a biocompatible sheath) using infrared technology rather than the thermocouple measurements employed by the CRT-2000 device. The use of infrared measurements does not affect the safety or effectiveness of the AlfaSight 9000 system for its intended use, as demonstrated by the completed bench testing, including Corvalent Design Verification Testing and Temperature Probe with Sheath Performance Testing.

The points measured for the AlfaSight 9000 systems are identical to the points measured by the CRT 2000 predicate device.

The following table provides more detailed information regarding the basis for the determination of substantial equivalence:

Parameter	AlfaSight 9000	CRT 2000 (K971956)
Intended Use / Indications for use	Adjunct diagnosis of: 1) abnormalities of the female breast; 2) peripheral vascular disease; 3) musculoskeletal disorders; 4) extracranial cerebral and facial vascular disease; 5) abnormalities of the thyroid gland; and 6) various neoplastic and inflammatory conditions. The AlfaSight 9000 is not intended to serve as a sole diagnostic screening procedure.	Adjunct diagnosis of: 1) abnormalities of the female breast; 2) peripheral vascular disease; 3) musculoskeletal disorders; 4) extracranial cerebral and facial vascular disease; 5) abnormalities of the thyroid gland; and 6) various neoplastic and inflammatory conditions. The CRT 2000 is not intended to serve as a sole diagnostic screening procedure.

Parameter	AlfaSight 9000	CRT 2000 (K971956)
Functionality	Captures skin surface temperatures, provides that data in a thermographic chart for use by the healthcare practitioner as an adjunct to other clinical procedures.	Captures skin surface temperatures, provides that data in a thermographic chart for use by the healthcare practitioner as an adjunct to other clinical procedures.
Where used	Doctor's Office, Clinic or Hospital	Doctor's Office, Clinic or Hospital
Anatomical Sites	Same	Same
Target Population/ demographic	Adult use, non pediatric	Adult use, non pediatric
Device Regulatory Classification	21 CFR 884.2980	21 CFR 884.2980
Product Code	LHQ	LHQ
Device Class	Class I	Class I
Biocompatibility	(Sheath) ISO 10993-1	Data Not Available
EMC and Safety	IEC 60601-1; IEC 60601-1-2	Data Not Available
510(k) number	To be determined	K971956
PC Supply voltage	AC 85 -264V	AC 110 - 240 V
PC Power Input	60 Watts	180 Watt
PC Frequency	Hz 47-63 Hz	Hz 50/60
PC Storage Temperature Range	-40°C to +85°C	0°C - 50°C
PC Screen Display	Graphic LCD Display	Graphic LCD Display
Probe Battery	Polymer Lithium-Ion	None
Probe Rechargeable	Yes	N/A
Probe Status Indicator	Yes	Yes
Probe Error Margin	+/-0.2 degrees C	+/-0.2 degrees C
Probe Temp. Collection method	Infrared thermocouple	bi-metal thermocouple
Probe Skin Contact	Sheathed probe tips contact the skin to start the temperature measurement. The IR sensor does not touch the skin.	Thermocouple sensor and edge surface of probe tip contact the skin to take the measurement. The sensor touches the skin.
Disposable Sheath Material	Polyethylene	N/A
Probe Optimum Range	25-40^{o}C	27-35^{o}C
Probe Communication	Blue Tooth Wireless Communication of measurement data from Probe to PC	Wired Communications

Parameter	AlfaSight 9000	CRT 2000 (K971956)
Software Main functions	Receives temperature signal and generates multiple point temperature measurement graphics for healthcare practitioners on measurement locations and temperature measurement readings.	Receives temperature signal and generates multiple point temperature measurement graphics for healthcare practitioners on measurement locations and temperature measurement readings.
Correct Orientation and location	Measurement points are highlighted on the figure on the display screen for measurement location and sequence of measurements.	Measurement points are highlighted on the figure on the display screen for measurement location and sequence of measurements.

PERFORMANCE TESTING

The AlfaSight 9000 System has been determined through engineering bench testing to be substantially equivalent to the predicate device. Testing demonstrates that the AlfaSight 9000 conforms to ISO 10993-1, IEC 60601-1, and IEC 60601-1-2.

The following non-clinical bench performance testing has been completed for the subject device:

- Biocompatibility
- Software Risk Analysis
- Software Requirements Specification
- Software Validation Protocol
- Software Verification Summary and Test Case Report
- Software Test Results Report and Revision History in
- Software Design Specification
- Software Development Environment Description Document
- Electromagnetic Compatibility and Electrical Safety

CONCLUSION

In sum, the results of non-clinical testing demonstrate that the AlfaSight 9000 System is as safe, as effective and performs as well as the predicate device. In sum, the AlfaSight 9000 is substantially equivalent to the CRT 2000 predicate device.