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

March 4, 2016

Securus, Inc.
Mr. William Gorman
Director of Quality and Regulatory Affairs
100 Cummings Center, Suite 215f
Beverly, Massachusetts 01915

Re: K152402
Trade/Device Name: InfraRed Thermographic System (IRTS)
IRTS Thermal Imaging Probe (TIP), IRTS Patient Monitoring Unit (PMU), IRTS Patient Interface Unit (PIU)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometers
Regulatory Class: II
Product Code: FLL
Dated: January 27, 2016
Received: February 2, 2016

Dear Mr. Gorman:

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,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K152402

Device Name

Infrared Thermographic System (IRTS)
IRTS Thermal Imaging Probe (TIP), IRTS Patient Monitoring Unit (PMU), IRTS Patient Interface Unit (PIU)

Indications for Use *(Describe)*

The IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) is intended to display continuous temperature measurements (C°) from the IRTS Thermal Imaging Probe.

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

K152402, INFRARED THERMOGRAPHIC SYSTEM (IRTS)

PREPARED: MARCH 3, 2016

1) Submitter

Securus Medical Group, Inc.
100 Cummings Center
Suite 215F
Beverly, MA 01915

Phone: 978-317-0836
Contact: William J. Gorman

2) Device

Trade name: InfraRed Thermographic System (IRTS)
IRTS Thermal Imaging Probe (TIP)
IRTS Patient Monitoring Unit (PMU)
IRTS Patient Interface Unit (PIU)

Common name: Clinical Electronic Thermometer

Classification Number/ Classification name/Product code:
Clinical Electronic Thermometers are Class II devices under 21 CFR § 880.2910 and are classified by the General Hospital Panel. Product code - FLL.

Special Controls:
Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers, March 1993

3) Predicate Device

ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, FIAB, (K123361)

4) Reference Device

S-Cath Esophageal Temperature Probe and Temperature Monitoring System, Circa Scientific, (K112376)

5) Device Description

The Securus InfraRed Thermographic System (IRTS) is an esophageal temperature probe and monitoring system intended for continuous temperature monitoring of the patient's esophagus. The Probe includes a thermocouple sensor for temperature monitoring and a thermographic sensor for thermal imaging. Data from both sensors are displayed on a monitor for the user.

The InfraRed Thermographic System (IRTS) consists of three components:

A. Thermal Imaging Probe (TIP or Probe)

B. Patient Interface Unit (PIU)

C. Patient Monitoring Unit (PMU)

The Probe provides esophageal temperature monitoring through the use of a standard thermocouple mounted in a flexible 9 French catheter. This design is standard for esophageal temperature probes commonly used in the industry. The Probe has been tested in compliance with ISO 80601-2-56:2009, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. In addition, the IRTS incorporates a thermographic sensor and fiber optic assembly to passively collect the infrared radiation that is self-emanating from the surrounding esophageal tissue surface. The thermal data is presented on the Patient Monitoring Unit as a two-dimensional color map with peak temperature over the mapped area. The thermal image and peak temperature are offered as additional temperature monitoring features. The thermal data of the IRTS is not classified under the Clinical Thermometer designation of ISO 80601-2-56.

6) Indications for Use

The IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) is intended to display continuous temperature measurements (C°) from the IRTS Thermal Imaging Probe.

7) Comparison to Predicate Device

The IRTS is substantially equivalent to the primary predicate device FIAB ESOTEST System (K123361). Both the subject device and the primary predicate device have the same intended use and indications for use as a continuous esophageal temperature monitor. Both use thermocouple sensors for temperature monitoring of the patients esophagus. The subject device also includes a thermographic sensor for displaying thermal images as an additional temperature monitoring feature. This feature does not raise different questions of safety or effectiveness as it provides additional information about the temperature in the patient's esophagus. Similar to reference device Circa Scientific, Esophageal Temperature Probe and Temperature Monitoring System (K112376), the subject device is provided non-sterile. Thus, the subject device has the same intended use and similar technological characteristics as the primary predicate device K123361. Any differences in technological characteristics do not raise different questions of safety or effectiveness. A summary comparison between the subject, primary predicate and reference devices is provided in the following table:

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361 **Primary Predicate Device**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System K 112376 **Reference Device**	SE Discussion
Intended Use	Continuous temperature monitoring of the patients esophagus	Continuous temperature monitoring of the patients esophagus.	Continuous esophageal temperature monitoring	Same intended use

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361 **Primary Predicate Device**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System K 112376 **Reference Device**	SE Discussion
Indications for Use	The IRTS Probe is intended for continuous esophageal temperature monitoring. The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.	The ESOTEST Probe is intended for continuous esophageal temperature monitoring. ESOTEST Monitor is intended to display continuous temperature measurement (°C) from 3 sensors temperature probe.	The Esophageal Temperature Probe is intended for continuous patient temperature monitoring. The radiopaque probe is designed for placement in the esophagus. Temperature Monitor: Display continuous temperature measurement (°C) from 12-sensor temperature probe.	Same indications as primary predicate
System Components	Temperature probe Patient Interface Unit Patient Monitoring Unit	Temperature probe Interconnect cable Patient Monitor	Temperature probe Interconnect cable Monitor	Similar components
Probe Sterility	Provided Non-sterile	Provided Sterile	Provided Non-sterile	Same as reference device
Probe Material (patient contact)	Polyethylene and platinum iridium	Polyurethane and stainless steel	Flexible Polyester and Rigid Pebax	Similar materials, tested for biocompatibility
Probe size	9 Fr catheter with 9 Fr sensor 150 cm length	7 Fr catheter with 11 Fr sensors 95 cm length	10 Fr OD, 30.5" total length. Interconnect Cable 10' long	Similar sizes
System Temperature Precision and Resolution	0.1° C	0.1° C	0.2° C	Similar precision and resolution.
Temperature Sensor	Type-T thermocouple	Type-T thermocouple	Thermistor	Similar sensor
Temperature Sensor Range	25° - 45° C	15°-75° C	25° - 45° C	Same range as reference device

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361 **Primary Predicate Device**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System K 112376 **Reference Device**	SE Discussion
Temperature Sensor Accuracy	± 0.3° C tested in accordance with ISO 80601-2-56	± 0.5° C tested in accordance with ISO 80601-2-56	± 0.3° C tested in accordance with ISO 80601-2-56	Better accuracy than primary predicate device
Transient Response Time of Temperature Sensor	Both heating transient response time and cooling transient response time are less than 2.5 seconds: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	Both heating transient response time and cooling transient response time are approximately 1 second: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	Heating transient 7 seconds, cooling transient 4.5 seconds tested in accordance with ISO 80601-2-56	Insignificant time differential.
Power Supply	100-240 Vac AC adaptor power supply 24 VDC	100-120/230 Vac	100-240 Vac	Compliant to US power supply
Electrical Safety and Electromagnetic Compatibility	Fully complies with IEC 60601-1:2005 +A1:2012 IEC 60601-1-2:2007	Fully complies with IEC UL 60601-1: 2006 IEC 60601-1-2:2007	Fully complies with IEC 60601-1:1998 (applicable sections)	Same standards

8) Performance Data

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

Biocompatibility:

Probes were tested in accordance with ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. Testing included:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity

Test results show that the device meets the requirements of ISO 10993 for its intended use.

Electrical Safety and EMC:

The InfraRed Thermographic System (IRTS) was tested in accordance with:

- AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and

a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

- IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

This testing demonstrates that the InfraRed Thermographic System (IRTS) meets the recognized standards for electrical safety and compatibility.

Software Verification and Validation:

Per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", Securus has provided appropriate software documentation based on Level of Concern. A system level software verification and validation protocol was developed to test each requirement. This protocol includes a cross-reference matrix to map each requirement with a test activity and a pass/fail criteria. Results of each test are recorded and compared to the pass/fail criteria. All software verification and validation activities show that the software meets product requirements documentation.

Performance Testing:

The InfraRed Thermographic System (IRTS) was tested in accordance with the requirements of ISO 80601-2-56 first Edition 2009-10-01: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. Testing included accuracy and response time. All performance testing data shows that the IRTS system meets the requirements of ISO 80601-2-56.

Mechanical Testing:

Finished devices were tested in accordance with pre-approved protocols based on design input requirements for mechanical strength and service life (simulated use). This testing shows that the IRTS system meets pre-established design input requirements for mechanical strength and service life when tested in simulated worst case conditions.

Conclusions

The IRTS has the same intended use, indications for use and similar technological characteristics as the primary predicate device K123361. Any difference in technological characteristics does not raise different questions of safety or effectiveness. The thermal imaging feature of the IRTS provides additional temperature monitoring of the patient's esophagus. The performance testing supports substantial equivalence of the IRTS to the predicate.