DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 9, 2017

First Sense Medical, LLC
% John J. Smith, M.D., J.D.
Regulatory Counsel
Hogan Lovells US LLP
555 13th Street, NW
WASHINGTON DC 20004

Re: K162767
Trade/Device Name: Sentinel BreastScan II System
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic system
Regulatory Class: I
Product Code: LHQ
Dated: December 14, 2016
Received: December 14, 2016

Dear Dr. 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,

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

Indications for Use Statement

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)*

K162767

Device Name

Sentinel BreastScan II System

Indications for Use *(Describe)*

The Sentinel BreastScan II System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare 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)*

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.

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"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

First Sense Medical, LLC's Sentinel BreastScan II System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

First Sense Medical, LLC
2001 Centerpoint Parkway, Suite 110
Pontiac, MI 48341

Phone: 248-392-3006
Facsimile: 248-876-9278

Contact Person: Alan Klevens, CEO

Date Prepared: September 30, 2016

Name of Device and Name/Address of Sponsor

Sentinel BreastScan II System

First Sense Medical, LLC
2001 Centerpoint Parkway, Suite 110
Pontiac, MI 48341

Common or Usual Name

Telethermographic System (Adjunctive Use)

Classification Name

Telethermographic System (Adjunctive Use)
Product Code: LHQ
21 C.F.R. 884.2980

Predicate Devices

Infrared Sciences Corp., BreastScan IR (K032350)

Purpose of the Special 510(k) Notice

The Sentinel BreastScan II System is a modification to the Infrared Sciences Corp. BreastScan IR system.

Device Description

The Sentinel BreastScan II System consists of a portable device that captures and records thermal infrared energy (heat) emitting from a person's body. There is no compression of the breast or patient contact with the device and the test emits no radiation to the patient. The device consists of a thermal camera, a metal enclosure to secure and protect components, a motor and electronics to raise and lower the tester to adjust the camera for various sized patients, a chair with attached armrests, adjustable special heat reflecting mirrors, a computer with a touchscreen monitor, data storage, software, and Wi-Fi communication. The tester includes an air cooling unit that blows cool air during part of the test cycle.

Intended Use / Indications for use

The Sentinel BreastScan II System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

Summary of Technological Characteristics

Telethermography is the technological principle for both the subject and predicate devices. Using an advanced non-contact infrared thermal camera, the Sentinel BreastScan II system records thermal data (emission of body temperature) from a patient's breasts. During the procedure, the patient sits facing a thermal camera, cool air is blown on the patient's breasts for part of the test and additional thermal data is recorded. The data is verified for errors, securely stored and made available to the healthcare professional or a third party reference lab for later processing and evaluation. The test procedure does not involve any compression or touching of the breasts and the patient has no contact with the tester.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Advanced digital Thermal Camera (FDA cleared).
- The Sentinel BreastScan II uses a FLIR A315 camera with a 45º lens at 2.5 ft. from the patient. The BreastScan IR uses a FLIR S40 camera with a 25º lens at 5 ft. from the patient. The FOV is the same for both cameras at patient chest.
- Test Sequence is the same for capturing thermal data and cooling patient.
- Tester housing contains computer, monitor(s), thermal camera, software and air cooling system equipment.
- Patient Chair with attached special (IR reflecting) mirrors to capture side images of breasts and custom armrests for proper patient positioning.
- Air Cooling System blows cool air onto patient breasts during test.

The following technological differences exist between the subject and predicate devices:

- The Sentinel BreastScan II System Tester housing is custom designed and includes motorized vertical travel for alignment of thermal camera and air cooling system with the patient. The BreastScan IR System Tester housing is a standard commercial cart containing the tester components at a fixed camera height. The vertical alignment of the patient is achieved by an adjustable chair.

- The Sentinel BreastScan II chair is a fixed height chair with vertically adjustable mirrors and armrests. The BreastScan IR chair is vertically adjustable with fixed mirrors and armrests.

- The Sentinel BreastScan II stores data securely in the cloud. The BreastScan IR stores data locally on the computer.

Performance Data

The Sentinel BreastScan II System was tested to and complies with the following standards:

- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 or IEC 60601-1 ed. 3.1 2012-08.
- [IEC] [60601-1-2:2007} Medical Electrical Equipment – Part 1-2 Requirements for Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances – Requirements and Tests} [2007}

The performance testing conducted for the thermal camera, system performance monitoring, software and the device functionality as a whole demonstrates that the device meets all Sentinel BreastScan II requirements and specifications as provided in the verification and validation testing results reports. In all instances, the Sentinel BreastScan II functioned as intended and the results observed and reported were as expected.

Conclusions

The Sentinel BreastScan II System has the same intended use and indications, principles of operation, and technological characteristics as the Infrared Sciences Corp. BreastScan IR. The minor differences in the Sentinel BreastScan II System's technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the Sentinel BreastScan II System is as safe and effective as the Infrared Sciences Corp., BreastScan IR. Thus, the Sentinel BreastScan II System is substantially equivalent to its predicate devices.