DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 1, 2016

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

Re: K160573
Trade/Device Name: FirstSense Breast Exam®
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic system
Regulatory Class: I
Product Code: LHQ
Dated: May 11, 2016
Received: May 11, 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

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)*

K160573

Device Name

FIRSTSense Breast Exam®

Indications for Use *(Describe)*

The FIRSTSense Breast Exam® device 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. It is intended for use in adult patient populations. 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)*

X 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

First Sense Medical, LLC's FIRSTSense Breast Exam®

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

First Sense Medical, LLC
2001 Centerpoint Parkway, Suite 110
Pontiac, MI 48341
Phone: 770-617-9416
Facsimile: 248-876-9278

Contact Person: Alan Klevens

Date Prepared: May 11, 2016

Name of Device and Name/Address of Sponsor

FIRSTSense Breast Exam®

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

Common/Classification Name

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

Predicate Device

Infrared Sciences Corp., BreastScan IR (K032350)

Intended Use / Indications for Use

The FIRSTSense Breast Exam® device 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. It is intended for use in adult patient populations. 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.

Device Description/Technological Characteristics

The FirstSense Breast Exam® system consists of a portable device (FSBE Tester) that captures and records thermal infrared energy (heat) emitting from a person's body. There is no compression of the breast or patient contact during a screening test. The device emits no radiation to the patient. The device consists of a thermal camera, a 3D camera, a tester main body consisting of metal and plastic to safely and securely house the electronic and mechanical components and motors (to adjust cameras for various sized patients), a computer, software components and two color monitors, as well as an air cooling unit that blows cool air during part of the screening test cycle. The FSBE system also contains a cloud server for safe storage of test data. During a screening test, the FSBE Tester's thermal camera acquires thermal images, and the 3D camera acquires depth data and visible light images of the patient breasts. When a test is completed, the acquired

data is uploaded to the FSBE system's cloud server, the FSM Central Server. The uploaded data becomes available to a physician when the FirstSense Data Viewer (FSDV) application downloads the data from the server to a local computer. The FSDV application allows the physician to view the thermal images, the 3D depth image and visible RGB images of the patient breasts. The depth and visible images are provided to the physician as additional information about the breasts with no quantitative data. When the FSDV application provides the thermal images, it allows the application user to select breast regions (nipple, areola, whole breast and breast quadrants) and regions of interest on the thermal views. The FSDV application provides temperature differential data between the left and right breast regions, and temperature differential data for the regions of interest before and after blowing cool air to the breasts in Test Summary report. The FSDV allows the application user to enter threshold values to be compared to the calculated temperature differential data. The FSDV provides comments in the Test Summary Report to indicate that the temperature differential data is within or above the entered threshold value. The FSDV does not include default threshold values and does not provide comments in the Test Summary report should the user choose not to enter threshold values.

Performance Data

The device performance was validated by conducting the following tests:

- The FSBE Tester was tested for its compatibility with both IEC 60601-1-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance, and IEC 60601-1-2, Medical Electrical Equipment Part 1-2: General requirements for basic safety and essential performance collateral standard: Electromagnetic compatibility.

- The FSBE Tester's mechanical parts and their expected performance are validated during full device validation, specifically during the verification of the device's pre-check routine which checks each device hardware component and its expected functionality. Also during execution of software functional verification tests, the performance of individual mechanical components are verified.

  The following verification tests were executed for full device validation:

  - FSDAQ software pre-check routine test – verifies the pre-check routine and integrity of device hardware components.
  - FSDAQ device log test – verifies the device log and software ability to record events related to test sequence and hardware status.
  - FSDAQ test sequence and error management – verifies the software for managing a test sequence and managing the errors, as well as verifies device hardware performance during the test sequence.
  - FSDAQ data storage and data upload – verifies software functionality for temporary test data storage and test data upload to the server.
  - FSDAQ patient positioning – verifies the software functionality to provide assistance to the operator to position the device before the test sequence. Also verifies the hardware components such as the 3D camera and its performance during patient positioning.

- The thermal camera performance is validated by executing the following thermal camera performance verification tests to evaluate the respective characteristics of the thermal camera:
  - Thermal Camera Uniformity Test;
  - Thermal Camera Drift Test;
  - Thermal Camera Calibration Verification and Bias Test;

- Thermal Camera Consistency Test;
- Thermal Camera Sensitivity Test;
- BBR Accuracy and Uniformity Test.

The above listed tests summarize the performance and the validation and verification activities conducted for the thermal camera, FSM Black Body Radiator, system performance, software and the device functionality. This testing demonstrates that the device meets all FIRSTSense Breast Exam® requirements and specifications. In all instances, the FIRSTSense Breast Exam® functioned as intended and the results observed and reported were as expected.

Substantial Equivalence

The FIRSTSense Breast Exam® has the same intended uses and indications, as well as similar technological characteristics and principles of operation as its predicate device. The minor technological differences between the FIRSTSense Breast Exam and its predicate device raise no new issues of safety or effectiveness. Thus, the FIRSTSense Breast Exam® is substantially equivalent.

A comparison table outlining similarities and differences of the subject device to the predicate device is provided below:

#	Feature	BreastScan IR™ (Predicate Device) K032350	FIRSTSense Breast Exam® (Subject Device)	Comments
1	Intended Use	The Infrared Sciences BreastScan IR™ 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.	The FirstSense Breast Exam® 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.	Same
2	Method of data collection	Non-contact passive infrared emissions	Non-contact passive infrared emissions	Same
3	Data processing	CPU with custom algorithms	CPU with custom algorithms	Same

#	Feature	BreastScan IR™ (Predicate Device) K032350	FIRSTSense Breast Exam® (Subject Device)	Comments
4	Collection instrument	Infrared camera	Infrared camera, 3D camera	Substantially Similar The FSBE system uses a 3D camera. The FSBE system includes a 3D camera for proper patient positioning and acquiring depth and visible image data during the screening test. The 3D camera helps the operator assure patient positioning before the test by providing a live patient image. The depth data and the visible image data is presented to the user as additional information (reference). The depth data and the visible image data does not provide any quantitative information. This minor difference raises no new safety or effectiveness concerns because of the above described reasons.
5	Measurement parameters	Allows for measurement of thermal emissions	Allows for measurement of thermal emissions	Same

#	Feature	BreastScan IR™ (Predicate Device) K032350	FIRSTSense Breast Exam® (Subject Device)	Comments
6	Storage	Hard disk	Hard disk and cloud server	Substantially Similar The predicate device uses a local hard drive for its data storage. The FSBE system uses a cloud server to assure long-term safe and secure storage of data. The data transferred to the cloud does not contain any personally identifiable patient information. The data transferred to the cloud only contains data acquired during the screening test. The data transfer occurs using an industry and government standard and digitally signed cryptographic certificates. This minor difference raises no new safety or effectiveness concerns because all information is encrypted, stored, backed up and maintained by a professional service.
7	Detector type	Focal plane array	Focal plane array	Same
8	Detector resolution	320 × 240 Pixels	320 × 240 Pixels	Same

#	Feature	BreastScan IR™ (Predicate Device) K032350	FIRSTSense Breast Exam® (Subject Device)	Comments
9	Thermal sensitivity	80 mK	50 mK	Substantially Similar The FSBE uses a thermal camera with a manufacturer-specified sensitivity of 50mK; this is slightly more sensitive than the 80mK specified by the BreastScan IR™. This minor difference in sensitivity of the thermal camera raises no new safety or effectiveness concerns as the camera has been validated as part of the subject system and meets all performance requirements.
10	Cooling device	Air conditioning unit	Air conditioning unit	Same
11	Camera output	14 bit digital	14 bit digital	Same
12	User Interface	A monitor is provided to view thermal images during the test. A keyboard and mouse is provided to the operator to enter the patient ID and start a test.	Two touchscreen monitors are provided (operator and patient) to view the thermal images during the test. A keyboard and mouse is provided to the operator to enter the patient ID and start a test.	Substantially Similar

#	Feature	BreastScan IR™ (Predicate Device) K032350	FIRSTSense Breast Exam® (Subject Device)	Comments
13	Result Reporting	BreastScan IR software allows the user to select breast regions (nipple, areola, whole breast, breast quadrants) and regions of interest (ROI). BreastScan IR provides the thermal views, and temperature differentials for the selected breast regions and ROIs. BreastScan IR provides report printing capability.	FirstSense Data Viewer (FSDV) software allows the user to select breast regions (nipple, areola, whole breast, breast quadrants) and regions of interest (ROI). FSDV provides the thermal views, and temperature differentials for the selected breast regions and ROIs. FSDV provides report printing capability.	Same

The subject device has the same intended use and characteristics as the predicate device. Documentation supplied in this submission demonstrates that any difference in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the First Sense Breast Exam® system is substantially equivalent to the predicate device.

Conclusions

- FIRSTSense Breast Exam® has the same intended use as the predicate device, Infrared Sciences BreastScan IR™ System, and therefore it may be found substantially equivalent;

- FIRSTSense Breast Exam® and the predicate device have the same indication statements;

- FIRSTSense Breast Exam® has similar technological characteristics as the predicate device, Infrared Sciences BreastScan IR™ System

- The subject device's new technological characteristics, such as the usage of a 3D camera to help the operator initially position the thermal camera and acquire visible images and 3D images during the test, do not raise any new questions of safety or effectiveness;

- Accepted scientific methods, *i.e.,* bench tests, demonstrated that the effects of the new characteristics do not raise any new questions of safety and effectiveness. Thus, the subject device is substantially equivalent.