July 16, 2019

UE LifeSciences Inc.
Mihir Shah
CEO
3401 Market St, Suite 200
Philadelphia, PA 19104

Re: K190575/S001
Trade/Device Name: iBreastExam Gen II
Regulation Number: 21 CFR 884.2990
Regulation Name: Breast Lesion Documentation System
Regulatory Class: II
Product Code: NKA
Dated: June 11, 2019
Received: June 12, 2019

Dear Mihir Shah:

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,

Sharon Andrews
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
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)*
K190575

Device Name
iBreastExam Gen II

Indications for Use *(Describe)*
iBreastExam Gen II device is intended to produce a surface pressure map of the breast as an aid in documenting palpable breast lesions identified during a clinical breast exam. iBreastExam Gen II device is intended for use by a qualified healthcare professional trained in its use and is not for home 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
iBreastExam Gen II (K190575)

Submitter's Name: UE LifeSciences Inc.
Address: 3401 Market St, Suite 200
Philadelphia PA 19104

Contact Person: Mihir Shah
Tel: 631.980.8340
Email: info@uelifesciences.com
Date Prepared: July 16, 2019

Product Trade Name	iBreastExam Gen II
Classification Number	21 CFR 884.2990
Classification Name	Breast Lesion Documentation System
Product Code	NKA
Regulatory Class	Class II
Predicate Device(s)	iBreastExam (K142926) The predicate device has not been subject to any design related recalls.

Description of the Device
iBreastExam Gen II is a visual mapping system, intended to produce a surface pressure map of the breast as an aid in documenting breast lesions identified during a clinical breast exam. The use of iBreastExam Gen II does not involve the use of any ionizing radiation.

Technological Characteristics:
The iBreastExam Gen II system consists of a group of hardware and software components.
The hardware component(s) consist of:

- iBreastExam Gen II Scanhead
- Computer System
- USB Wall Charger and Charging Cables

The software component(s) consist of:

- iBEConnect Software Program

Key Components and Functions:

Component	Function
iBreastExam Gen II Scanhead	To collect size, location, shape and stiffness data from the breast surface.

Computer System	To receive, store, display and print lesion documentation data.
USB Wall Charger and Charging Cables	To recharge the iBreastExam Gen II Scanhead and the Computer System.
iBEConnect Software Program	To provide a user with the ability to create tactile map of the breasts. The software also provides an interface with the database in the system and the ability to add, modify, retrieve and delete patient and exam data including the tactile maps. The software can also be used to generate reports.

Table 1: Key components and functions

Device Characteristics:

- Use Type: Repeat Use
- Sterilization: Non-sterile
- Software: Yes
- Coatings/Additives: No
- Power Sources: Battery Powered during use
- Patient Contacting Material: ABS
- Type of Contact: Skin surface (breast)
- Duration of contact: 5-10minutes
- Environment of use: Physician's Office, Hospital, Primary Care

The device is intended to produce a surface pressure map of the breast as an aid in documenting size, shape, and location of breast lesions identified during a clinical breast exam. It is a documentation tool. It is not intended for diagnosis. The device should only be used to document a lesion already palpated on clinical breast exam. Clinical management decisions should only be made on the basis of the clinical and diagnostic examinations (e.g. ultrasound or mammography). If there is a disagreement between the examination and the record produced by the device, decisions should be made on the basis of the clinical examination.

Sterilization and Shelf Life:

The iBreastExam Gen II device does not have any sterilization requirements. The scanhead should be cleaned and disinfected by wiping twice with medical grade alcohol wipes (70% Isopropyl Alcohol) before and after each use. The iBreastExam Gen II system does not require any special storage conditions for the device. The storage conditions do not affect the device safety or effectiveness. The device does not have any specific shelf-life.

Principle and Theory of Operation:

iBreastExam Gen II system consists of a Scanhead which houses an array of capacitive pressure sensors. These pressure sensors measure tissue elasticity by making micro-palpations on the surface of the breasts and by differentiating the variations in tissue stiffness. In that, the hard or

stiff areas will produce a response (depicted by red color on computer screen) as compared to fatty, glandular breast tissue (depicted by green color on computer screen). The amount of resistance offered by the breast tissues will be directly converted to voltage as measured by the sensing portion of the capacitive pressure sensors.

The breast lesion documentation procedure can only be performed after the Scanhead has an established Bluetooth wireless connection with the Computer, which is indicated on the Computer screen. The iBEConnect Software Program provides software-based positioning guidance to the user in order to perform the procedure. Tactile maps generated from the pressure data during the procedure can be displayed, stored, reviewed and printed using the iBEConnect Software Program.

Functional Performance Characteristics & Requirements:

Hardware Controls & Indicators	**Description**
Computer on/off button	The on/off button of the computer system switches on the Computer system
Scanhead On/Off button	The On/Off button applies power to the scan head. When the control is in the On position, the physician can place the scan head on the breast and capture images. If it is in the Off position then the device cannot be used.
Blue LED	The Blue LED is located between the mini-USB charging port and the ON/OFF button on the Scanhead. It indicates whether the Scanhead is charging or not. When, the Scanhead is plugged in and the blue LED is ON, it indicates that the Scanhead is charging. The blue LED is turned off while not charging.

Table 1: Hardware controls and indicators

iBreastExam Gen II System software controls and indicators as described in the table below:

Software Controls and Indicators	Description
Graphical User Interface	The iBEConnect Software Program provides the graphical user interface to operate the iBreastExam Gen II System.
Calibrate	iBreastExam Gen II Scanhead must be calibrated before each use. The calibration establishes that, a baseline reading is obtained from the breast tissue by selecting a lesion-free breast area and that the pressure sensors are performing within the acceptable range of factory calibration.
Normal Scan Mode	In this mode, the user follows the software guided positioning routine to perform the procedure.
Quick Scan Mode	In this mode, the software guided positioning routine is disabled, allowing the operator to select specific locations of interest.

Table 2: Software controls and indicators

Indications for Use

iBreastExam Gen II device is intended to produce a surface pressure map of the breast as an aid in documenting palpable breast lesions identified during a clinical breast exam. iBreastExam Gen II device is intended for use by a qualified healthcare professional trained in its use and is not for home use.

The indications for use statement of the subject device is unchanged from the predicate device; accordingly, the subject and predicate device have the same intended use.

Comparison of Technological Characteristics

A substantial equivalence table below compares iBreastExam Gen II and the predicate devices, iBreastExam (K142926) and outlines the similarities and the differences.

FDA K#	iBreastExam Gen II (K190575)	iBreastExam (K142926)
Regulation #	21 CFR Section 884.2990	21 CFR Section 884.2990
Device Class	Class II	Class II
Product Code	NKA	NKA
Classification Name (Reg #)	Breast Lesion Documentation System	Breast Lesion Documentation System
Intended Use	To produce a surface pressure map of the breast as an aid to document palpable breast lesions identified and/ or monitored during a clinical breast exam.	To produce a surface pressure map of the breast as an aid to document palpable breast lesions identified and/ or monitored during a clinical breast exam.
Processing unit	Computer with software, Windows based operating system	Computer with software, Windows based operating system
Data Acquisition Method	Array of pressure sensors mounted on hand-held scanhead	Array of pressure sensors mounted on hand-held scanhead
Lesion characterization	Lesion size, Lesion location, Lesion stiffness, Lesion shape	Lesion size, Lesion location, Lesion stiffness, Lesion shape
Number of sensors in imaging component	648	16
Lesion Documentation	Yes	Yes
Detectable lesion size	5mm and above	5mm and above

Pressure Sensor Array Size	40mm x 35mm	28mm x 28mm
Imaging component cover	Yes	Yes
Position orientation Reference	Software based positioning system	Software based positioning system
Monitor	Color monitor	Color monitor
Printer	Optional, can be connected to any inkjet printer if required	Optional, can be connected to any inkjet printer if required
Lotion	No	No
Keyboard and mouse	Keyboard/touch	Keyboard/touch
Display images	Yes	Yes
Storage of images	Yes	Yes
Printed Hardcopy of images	Yes	Yes
Comparison to previous images	No	No
Final report	Color Tactile Maps	Color Tactile Maps
Prescription or OTC	Prescription	Prescription
Intended users	Healthcare professionals	Healthcare professionals
Intended Environment	Physician’s office or clinic	Physician’s office or clinic
Sterile components	None	None

Method of sterilization	None	None
Cleaning method	Commercially available medical grade alcohol (70% isopropyl alcohol) wipes	Commercially available medical grade alcohol (70% isopropyl alcohol) wipes

Table 4: Substantial Equivalence Table

Differences in Technological Characteristics:

Differences in Technological Characteristics	Explanation
Number of sensors in imaging component: 648 pressure sensors in iBreastExam Gen II vs. 16 pressure sensors in predicate iBreastExam (K142926)	While the iBreastExam Gen II system consists of more sensors compared to predicate iBreastExam (K142926), the output of iBreastExam Gen II system is identical to that of predicate iBreastExam (K142926).
Pressure Sensor Array Size: 40mm x 35mm in iBreastExam Gen II vs. 28mm x 28mm in iBreastExam (K142926)	This is a minor design difference and the difference in pressure sensor array size does not raise any further concern related to safety or effectiveness for the iBreastExam Gen II system.

Table 5: Difference in technological characteristics

The differences in technological characteristics do not raise different questions of safety and effectiveness.

Performance Testing

Performance tests were conducted per Class II Special Controls Guidance Document: Breast Lesion Documentation System - Guidance for Industry and FDA Staff. The testing procedures include bench tests, electrical and mechanical safety tests and electromagnetic compatibility tests. In addition, a side-by-side performance test was conducted between subject device (K190575) and the predicate device, iBreastExam (K142926).

Consistent with FDA's guidance document titled "Use of Standards in Substantial Equivalence Determinations" (March 12, 2000), "Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards" (September 17, 2007), iBreastExam Gen II complies with the following recognized consensus standards:

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012: Medical Electrical Equipment - Part 1: General Requirements for Safety (general electrical safety test)
- IEC 60601-1-2: 2014 (Fourth edition): Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (radiated emission, electrostatic discharge, radiated immunity (including proximity field immunity), and power frequency magnetic field immunity)

Complete validation and verification were performed on all software and hardware subsystems. In summary, all test results were satisfactory and did not raise any additional safety or effectiveness concerns.

Performance bench tests were conducted for Inter- observer, Intra- observer and inter- system accuracy and reproducibility to measure object size, shape and stiffness. Side-by-side testing between the iBreastExam Gen II and its predicate device iBreastExam (K142926) was conducted to determine the accuracy of the results. Tests relating to various conformity standards were also performed to ensure low risk to the patient and user. Each test procedure hypothesis, methods and conclusions are briefly described below:

Type	Bench Test
Testing Procedure	Inter-observer accuracy and reproducibility
Hypothesis	Different observers obtain reproducible results on the same phantom using the same iBreastExam Gen II device.
Method(s)	For this validation, 20 subjects were recruited to perform the iBreastExam Gen II procedure on the silicone phantoms. The silicone phantoms were constructed by layering two individual slabs of silicon, one measuring 20cm x 12.5cm x 1cm, and the other measuring 20cm x 12.5cm x 2 cm. The silicone slabs were placed on top of each other, with the lesions placed in between. Depending on which slab was placed on top, the lesion would either be 1cm or 2cm beneath the surface. Each recruit was instructed on how to use iBreastExam Gen II and was allowed to perform several practice exams prior to the study. Each recruit performed iBreastExam Gen II tests using the same device. This test measures the ability of a single iBreastExam Gen II unit to measure the location, size, stiffness, and shape with respect to the defined lesion scenario across all the recruits.
Conclusion(s)	iBreastExam Gen II produced accurate and reproducible results.

Table 6:Inter-Observer Tests

Type	Bench Test
Testing Procedure	Intra- observer accuracy and reproducibility
Hypothesis	The results obtained from the same iBreastExam Gen II device and a single user are reproducible for the same phantoms.

Method(s)	For this validation, 20 subjects were recruited to perform the iBreastExam Gen II procedure on the silicone phantoms. The silicone phantoms were constructed by layering two individual slabs of silicon, one measuring 20cm x 12.5cm x 1cm, the other measuring 20cm x 12.5cm x 2cm. The silicone slabs were placed on top of each other, with the lesions placed in between. Depending on which slab was placed on top, the lesion would either be 1cm or 2cm beneath the surface. Each recruit was instructed on how to use iBreastExam Gen II and was allowed to perform several practice exams prior to the study. Each recruit performed iBreastExam Gen II tests using the same device. This test measures the ability of a single iBreastExam Gen II unit to measure the location, size, stiffness, and shape with respect to the defined lesion scenario for the same recruit.
Conclusion(s)	iBreastExam Gen II produced accurate and reproducible results.

Table 7: Intra-Observer Test

Type	Bench Test
Testing Procedure	Inter-system accuracy and reproducibility
Hypothesis	The results obtained from different iBreastExam Gen II devices and user pairs are reproducible for the same phantoms.
Method(s)	For this validation, 20 subjects were recruited to perform the iBreastExam Gen II procedure on the silicone phantoms. The silicone phantoms were constructed by layering two individual slabs of silicon, one measuring 20cm x 12.5cm x 1cm, the other measuring 20cm x 12.5cm x 2cm. The silicone slabs were placed on top of each other, with the lesions placed in between. Depending on which slab was placed on top, the lesion would either be 1cm or 2cm beneath the surface. Each recruit was instructed on how to use iBreastExam Gen II and was allowed to perform several practice exams prior to the study. Each recruit performed iBreastExam Gen II tests using two different devices. This test measures the ability of a multiple iBreastExam Gen II units to measure the location, size, stiffness, and shape with respect to the defined lesion scenario for the same recruit.
Conclusion(s)	iBreastExam Gen II produced accurate and reproducible results.

Table 8: Inter-System Test

Conclusion

Performance testing provided above support substantial equivalence determination. The tests demonstrate that the subject device (K190575) is as safe, as effective, and performs as well as or better than the legally marketed predicate device, iBreastExam (K142926).