June 28, 2019

Sure, Inc.
Laurence Harvey
Senior Quality Engineer
Certified Compliance Solutions
11665 Avena Place, Suite 203
San Diego, CA 92128

Re: K181672
Trade/Device Name: SureTouch Mobile Pressure Mapping System
Regulation Number: 21 CFR§ 884.2990
Regulation Name: Breast Lesion Documentation System
Regulatory Class: II
Product Code: NKA
Dated: May 17, 2019
Received: May 28, 2019

Dear Laurence Harvey:

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 M. Andrews
Assistant 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)*
K181672

Device Name
SureTouch Mobile Pressure Mapping System

Indications for Use *(Describe)*
The SureTouch Mobile Pressure Mapping System is intended to produce a surface pressure map of the breast as an aid in documenting palpable breast lesions identified during a clinical breast examination. The SureTouch Mobile Pressure Mapping System 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
K181672 - SureTouch Mobile Pressure Mapping System

Submitter: Sure, Inc
Address: 1404 Granvia Altamira
Palos Verdes Estates, CA. 90274
Phone number: (833) 787-3642

Contact person: David Ables, CTO
Phone number: (833) 787-3642 x 701

Date prepared: June 25, 2019

Trade name: SureTouch Mobile Pressure Mapping System
Common Name: Documentation System for Breast Lesions
Regulation Number: 21 CFR 884.2990
Regulation Name: Breast Lesion Documentation System
Product Code: NKA (System, Documentation, Breast Lesion)
Regulatory Class: Class II

Predicate Device: BreastView Visual Mapping System (DEN020001). This predicate device has not been subject to any design related recalls.

Device Description:

The SureTouch Mobile Pressure Mapping System ("SureTouch") is a computer-based device that produces a pressure map, called a tactile image, of specific areas of the breast as an aid to document lesions detected during a clinical breast exam. SureTouch utilizes a rechargeable, battery-powered hand-held wand (sensor unit) that incorporates a 30 x 40 mm array of pressure sensing elements to collect tactile data as the device is moved across the breast. Data collected using the wand are wirelessly transferred to the tablet display where they are used to generate tactile images and provide information on a lesion's size, shape and hardness. The final report includes a tactile image of each lesion along with its user inputted location. The SureTouch System also includes a calibration and training phantom, a scale to ensure correct force applied during calibration procedures, and a holder for the wand.

Indications for Use:

The SureTouch Mobile Pressure Mapping System is intended to produce a surface pressure map of the breast as an aid in documenting palpable breast lesions identified during a clinical breast examination. The SureTouch Mobile Pressure Mapping System is intended for use by a qualified healthcare professional trained in its use and is not for home use.

Comparison of Subject and Predicate Devices:

Parameter	Subject Device SureTouch System K181672	Predicate Device BreastView Visual Mapping System (DEN020001)	Comparison
Indications for Use	The SureTouch Mobile Pressure Mapping System is intended to produce a surface pressure map of the breast as an aid in documenting palpable breast lesions identified during a clinical breast examination. The SureTouch Mobile Pressure Mapping System is intended for use by a qualified healthcare professional trained in its use and is not for home use.	The Breast View Visual Mapping System is intended for use in producing a surface map of the breast as an aid to document palpable breast lesions identified during a clinical breast examination.	The subject and predicate devices have the same intended use.
Sensor	Handheld sensor unit containing a 30 x 40 mm rectangular array of 192 sensors.	Handheld sensor unit containing a 25 x 40 mm array of 416 sensors.	**Different –** The predicate device has a greater number of sensors than the subject device. Differences in sensor numbers do not raise different questions of Safety and Effectiveness (S&E)
Display	Android-based touchscreen tablet that controls device functions and displays exam information.	Windows-based PC that controls device functions and displays exam information.	**Different –** The subject and predicate devices use different display types. This difference does not raise different questions of S&E.
Calibration/Training Pad and Scale	Yes – pad includes simulated lesions for training and is also	No	**Different –** The subject device is provided with a

	used for device calibration in conjunction with the provided scale.		standalone pad and scale that are used for calibrating the device. These differences do not raise different questions of S&E.
Lesion Documentation	Lesion size, hardness, shape and user-inputted location	Lesion size, stiffness, shape, and location.	**Different** – The predicate device includes an automated lesion location position system that is not part of the subject device that requires the user to manually identify the location of a specific lesion on the display screen. This difference does not raise different questions of S&E.
Detectable Lesion Size	5mm to 25x 35 mm	5-40 mm	**Similar**
Disposable Sheath and Lotion Use	Device to be used with a polyurethane sheath and lotion. Specifications for suitable, commercially-available sheaths and lotion provided in labeling	Device to be used with a polyurethane sheath and lotion.	**Same**

As shown above, the indications for use of the subject and predicate devices are not identical; however, their intended uses are the same (i.e., documenting palpable breast lesions detected during a clinical breast exam).

Regarding technological characteristics, the subject and predicate devices have similarities in their general designs. However, differences do exist as described in the table above (e.g., sensor number, display types, etc.). The differences identified do not raise different questions of safety and effectiveness as compared to the predicate device as stated in the table.

Performance Testing:

The following tests have been conducted to ensure reliable design and performance under the specified testing parameters. These tests include:

- Software information that met the recommendations for a minor level of concern software per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

- Cybersecurity information that met the recommendations in the FDA guidance document, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."

- Electrical safety testing per ANSI/AAMI EN60601-1:2006+A11:2013+A12:2014

- Electromagnetic compatibility testing per IEC 60601-1-2:2007 (3rd edition)

- Wireless technology information that met the recommendations in the FDA guidance document "Radio Frequency Wireless Technology in Medical Device."

- Intra and inter-observer, and inter-system accuracy and reproducibility testing as described in the FDA "Class II Special Controls Guidance Document: Breast Lesion Documentation System." Testing met all acceptance criteria.

- Force gauge validation: Testing to assess the accuracy and reproducibility of the force gauge shown on the device display that is used for device calibration and to assess force applied during an exam. Testing met all acceptance criteria.

- Algorithm output sensitivity: Testing to assess sensitivity of the device algorithms to calibration errors. Testing met all acceptance criteria.

- Phantom testing:

    - Testing to assess accuracy of sensor measurement when placed under a uniform calibration force as compared to calibration force applied using the phantom and scale. Testing met all acceptance criteria.

    - Testing to demonstrate that aging of the calibration and training pad did not impact device calibration results. Testing met all acceptance criteria.

Conclusion:

The results of the performance testing described above demonstrates that the subject device is as safe and effective as the predicate device and supports a determination of substantial equivalence.