Siemens Medical Solutions, Inc
Denise Adams
Regulatory Affairs Specialist
40 Liberty Boulevard 65-1A
MALVERN, PA 19355

February 6, 2018

Re: K172832
Trade/Device Name: Insight BD
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: February 1, 2018
Received: September 19, 2017

Dear Denise Adams:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172832

Device Name
Insight BD

Indications for Use *(Describe)*
Insight BD is a software application for the volumetric density assessment of digital x-ray images of the breast to aid health care professionals in the assessment of breast tissue composition. Insight BD is not a diagnostic aid and should be used only as adjunctive information when the final assessment of breast density category is made visually by medical professionals.

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: Insight BD

Company Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355

Date Prepared December 15, 2017

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. General Information

Importer/Distributor
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355
Establishment Registration Number: 2240869

Location of Manufacturing Site
Siemens Healthcare GmbH
Siemensstr. 1
91031 Forchheim, Germany
Establishment Registration Number: 3004977335

2. Contact Person

Denise Adams, RAC
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355
adams.denise@siemens-healthineers.com

Alternate Contact Person
Patricia D. Jones, RAC
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355
patricia.d.jones@siemens-healthineers.com

3. Device Name and Classification

Trade Name	Insight BD
Classification Name	System, Image Processing, Radiological
Classification Panel	Radiology
Classification Regulation	21 CFR §892.2050
Device Class	Class 2
Product Code	LLZ

4. Legally Marketed Predicate Device

Trade Name	Volpara Imaging Software
510(k) #	K152028
Clearance Date	10/26/2015
Classification Name	System, Image Processing, Radiological
Classification Panel	Radiology
Classification Regulation	21 CFR §892.2050
Device Class	Class 2
Product Code	LLZ
Recall Information	This device has not been subject to a design-related recall

5. Device Description

The Siemens volumetric breast density analysis application software Insight BD provides volumetric assessment of digital x-ray images of the breast, including both digital mammograms and raw tomosynthesis projection images.

The assessment consists of generating and evaluating density maps where the value at each pixel represents the thickness of fibroglandular tissue above that pixel. From those density maps the software calculates quantitative values, namely

- volume of fibroglandular tissue in the breast in cm^3
- breast volume in cm^3
- volumetric breast density in %
- breast density grade

The breast density grade is computed by thresholding of the volumetric breast density and conforms to BI-RADS® 5th Edition breast composition categories. The masking effect of dense fibroglandular tissue is automatically included in the results.

Insight BD is a software option for the Siemens digital mammography systems. Insight BD may be installed either on Siemens released PC hardware or on the Siemens digital mammography systems. Breast Density results are stored in the DICOM header and can be used for further documentation.

6. Indications for Use

Insight BD is a software application for the volumetric density assessment of digital x-ray images of the breast to aid health care professionals in the assessment of breast tissue composition. Insight BD is not a diagnostic aid and should be used only as adjunctive information when the final assessment of breast density category is made visually by medical professionals.

7. Substantial Equivalence

The Siemens Insight BD volumetric breast density application software is substantially equivalent to the commercially available Volpara Imaging Software (K152028).

The Insight BD has the same intended use, fundamental scientific technologies and performance characteristics as the predicate device Volpara Imaging Software and the performance of the Insight BD application software has been verified with similar tests as the predicate. The substantial equivalence comparison table below compares the main performance data of the subject device Siemens Insight BD to the cleared predicate Volpara Imaging Software (K152028).

Features / Technology	Subject Device Insight BD	Predicate Device Volpara Imaging Software K152028	Remarks
Indications for Use	Insight BD is a software application for the volumetric density assessment of digital x-ray images of the breast to aid health care professionals in the assessment of breast tissue composition. Insight BD is not a diagnostic aid and should be used only as adjunctive information when the final assessment of breast density category is made visually by medical professionals.	Volpara is a software application intended for use with the raw data from digital breast x-ray systems, including tomosynthesis. Volpara calculates a density map and from that determines volumetric breast density as a ratio of fibroglandular tissue and total breast volume estimates. Volpara provides these numerical values along with a BI-RADS breast density 4th or 5th Edition category to aid health care professionals in the assessment of breast tissue composition. Volpara produces adjunctive	Same meaning, only wording is different

Features / Technology	Subject Device Insight BD	Predicate Device Volpara Imaging Software K152028	Remarks
		information. It is not an interpretive or diagnostic aid.	
Intended Users	Health Care Professionals	Health Care Professionals	Same
Image Source	Digital mammograms from • mammography or • tomosynthesis systems	Digital mammograms from • mammography or • tomosynthesis systems	Same
Anatomical Area	Breast	Breast	Same
Assessment Scope	Volumetric	Volumetric	Same
Operating Environment	Windows	Windows	Same
Image Storage and Report Generation	Yes Output to the console	Yes Output to the console	Same
Numeric Output	• Volume of Fibroglandular tissue • Volume of Breast • Volumetric Breast Density • Siemens Breast Density Grade corresponding to BI-RADS® 5th Edition Breast Density Category	• Volume of Fibroglandular tissue • Volume of Breast • Volumetric Breast Density • Volpara Density Grade corresponding to BI-RADS® 4th and 5th Edition Breast Density Category	Siemens volumetric breast density information corresponds to BI-RADS® 5th Edition breast density category only
Storage of Breast Density Information in Image	Yes	No	Siemens volumetric breast density information is stored in the DICOM header
Classification	21 CFR 892.2050; LLZ	21 CFR 892.2050; LLZ	Same
Software Level of Concern	Moderate	Moderate	Same

8. Summary of Technological Characteristics of Subject Device as Compared with the Predicate Device

The Insight BD software is based on similar technology and algorithms to calculate the volumetric density as the predicate Volpara Imaging Software.

9. Performance Data

The Siemens Insight BD has been verified and validated according to the company's design control process. A risk analysis compliant with ISO 14971 has been provided and incorporated into the development effort. Software testing included both unit level and integrated system level testing.

The device was tested and determined to be compliant to the following standards:

ISO 14971	Medical devices – Application of risk management to medical devices
ISO 62304	Medical device software – Software life cycle processes
NEMA PS 3.1-3.20	Digital Imaging and Communications in Medicine (DICOM) Set

Density parameters were evaluated using various image data sets and results were compared against predicate performance, when appropriate.

- Measurement accuracy was assessed by comparing Insight BD estimates with known values from breast phantoms.
- Reproducibility was assessed by running Insight BD over substantial data sets and the results for left and right breasts and CC and MLO views were compared to confirm that the results were similar for each view and each breast.
- Reproducibility was assessed by running Insight BD over substantial data sets where the same woman had been imaged on Siemens mammography systems in both tomosynthesis (DBT) and mammography (FFDM) modes, and the results were compared to confirm they were similar.
- Reproducibility was assessed by running Insight BD over substantial datasets where the same women had been imaged on Siemens units running in both mammography and PRIME modes and the results were compared to confirm they were similar.
- Consistency was assessed by running Insight BD over substantial datasets where the women's age was known and results were compared with the expected and known decrease in breast density with age.
- Relationship to visual assessment was assessed by running Insight BD over x-ray images for which a BI-RADS® 5th Edition density category was available from MQSA qualified radiologists followed by a comparison of the two sets of data.
- Equivalence was assessed by running both the predicate device Volpara and Insight BD over substantial datasets and the results were compared to confirm they were similar.

10. General Safety and Effectiveness Concerns

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software means, user instructions, verification and validation testing to ensure that the product meets its intended uses.

11. Conclusion as to Substantial Equivalence

The Siemens volumetric breast density analysis application software Insight BD has the same intended use, fundamental scientific technology and performance characteristics as the predicate device. The 510(k) premarket notification for Insight BD contains adequate information and data to demonstrate substantial equivalence to the predicate device.