DeepHealth, Inc.
℅ B. Nathan Hunt
VP, Quality Assurance and Regulatory Affairs
1000 Massachusetts Avenue
CAMBRIDGE MA 01238

May 12, 2022

Re: K220105
 Trade/Device Name: Saige-Dx
 Regulation Number: 21 CFR 892.2090
 Regulation Name: Radiological computer assisted detection and diagnosis software
 Regulatory Class: Class II
 Product Code: QDQ
 Dated: May 2, 2022
 Received: May 4, 2022

Dear B. Nathan Hunt:

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 and Part 809); 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,

For

Michael D. O'Hara, Ph.D.
Deputy Director
DHT8C: Division of Radiological Imaging and Radiation
 Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) Number *(if known)*
K220105

Device Name
Saige-Dx

Indications for Use *(Describe)*
Saige-Dx analyzes digital breast tomosynthesis (DBT) mammograms to identify the presence or absence of soft tissue lesions and calcifications that may be indicative of cancer. For a given DBT mammogram, Saige-Dx analyzes the DBT image stacks and the accompanying 2D images, including full field digital mammography and/or synthetic images. The system assigns a Suspicion Level, indicating the strength of suspicion that cancer may be present, for each detected finding and for the entire case. The outputs of Saige-Dx are intended to be used as a concurrent reading aid for interpreting physicians on screening mammograms with compatible DBT hardware.

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.

K220105
510(k) Summary
DeepHealth, Inc.
Saige-Dx

In accordance with 21 CFR 807.92 the following summary of information is provided, on this date, May 10, 2022:

1. 510(k) SUBMITTER

DeepHealth, Inc.
1000 Massachusetts Avenue
Cambridge, MA 02138
Tel: 424-832-1480

Contact Person:

B. Nathan Hunt
Vice President, Quality Assurance and Regulatory Affairs
DeepHealth, Inc.
1000 Massachusetts Avenue
Cambridge, MA 02138
Tel: 424-832-1480

Date Prepared:

May 10, 2022

2. DEVICE

Trade Name of Device: Saige-Dx

Common or Usual Name: Medical Image Software

Regulation Name and Number:
Radiological Computer Assisted Detection and Diagnosis Software (21 CFR 892.2090)

Regulation Class: II

Product Code: QDQ

3. PREDICATE DEVICE

Trade Name: Transpara™

Common Name or Usual Name: Medical Image Software

Regulation Name and Number:
Radiological Computer Assisted Detection and Diagnosis Software (21 CFR 892.2090)

Regulation Class: II

Product Code: QDQ

510(K) No.: K181704

4. DEVICE DESCRIPTION

Saige-Dx is a software device that processes screening mammograms using artificial intelligence to aid interpreting radiologists. By automatically detecting the presence or absence of soft tissue lesions and calcifications in mammography images, Saige-Dx can help improve reader performance, while also reducing reading time. The software takes as input a set of x-ray mammogram DICOM files from a single digital breast tomosynthesis (DBT) study and generates finding-level outputs for each image analyzed, as well as an aggregate case-level assessment. Saige-Dx processes both the DBT image stacks and the associated 2D images (full-field digital mammography (FFDM) and/or synthetic 2D images) in a DBT study. For each image, Saige-Dx outputs bounding boxes circumscribing any detected findings and assigns a Finding Suspicion Level to each finding, indicating the degree of suspicion that the finding is malignant. Saige-Dx uses the results of the finding-level analysis to generate a Case Suspicion Level, indicating the degree of suspicion for malignancy across the case. Saige-Dx encapsulates the finding and case-level results into a DICOM Structured Report (SR) object containing markings that can be overlaid on the original mammogram images using a viewing workstation and a DICOM Secondary Capture (SC) object containing a summary report of the Saige-Dx results.

5. INDICATIONS FOR USE

Saige-Dx analyzes digital breast tomosynthesis (DBT) mammograms to identify the presence or absence of soft tissue lesions and calcifications that may be indicative of cancer. For a given DBT mammogram, Saige-Dx analyses the DBT image stacks and the accompanying 2D images, including full field digital mammography and/or synthetic images. The system assigns a Suspicion Level, indicating the strength of suspicion that cancer may be present, for each detected finding and for the entire case. The outputs of Saige-Dx are intended to be used as a concurrent reading aid for interpreting physicians on screening mammograms with compatible DBT hardware.

Intended User Population

The intended users of Saige-Dx are interpreting physicians qualified to read screening mammography exams.

Intended Patient Populations

The device is intended to be used on women thirty-five (35) years of age or older undergoing screening mammography.

Warnings and Precautions

Saige-Dx is an adjunct tool and is not intended to replace a physician's own review of a mammogram. Decisions should not be made solely based on analysis by Saige-Dx.

6. PREDICATE DEVICE COMPARISON

Saige-Dx and the predicate device have similar indications for use, patient population, technical characteristics, and principles of operation. The differences between Saige-Dx and the predicate device do not alter the suitability or of the subject device for its intended use.

The devices are intended to be used by physicians to aid in the interpretation of screening mammograms. The devices are not intended to be used as a replacement for a full physician review or their own clinical judgement.

The design of Saige-Dx is similar to that of the predicate device. Both devices detect and characterize findings in radiological breast images and provide information regarding the presence and location of the findings to the user. As both devices use proprietary algorithms, there are assumed differences in the algorithmic components, as well as minor differences in the specific formats of the outputs provided to users.

Non-clinical and clinical testing has been completed ensuring that the differences do not affect the safety and effectiveness of the proposed subject device.

7. PERFORMANCE DATA

Saige-Dx is a software device and has been determined of Moderate Level of Concern. Verification testing included software unit testing, software integration testing, and system testing. Testing confirmed that the software, as designed and implemented, satisfies the software requirements.

Validation of the software was performed using two retrospective studies as described below. The data used in the validation testing was obtained from different clinical sites than that used for Saige-Dx AI algorithm training. DeepHealth ensured that there was no overlap between the data used to train and test the Saige-Dx AI algorithm. The data used to train the Saige-Dx algorithm consisted of six datasets across various geographic locations in the US and the UK, including diverse regions such as New York City.

Performance Testing: Reader Study

A fully balanced, multi-reader multi-center (MRMC) reader study was conducted to evaluate the performance of 18 MQSA qualified radiologists when reading a set of retrospectively collected DBT mammogram exams with and without the aid of Saige-Dx. The primary objective was to compare breast cancer detection performance of radiologists reading with the aid of Saige-Dx versus without Saige-Dx. Each radiologist read 240 cases twice in two reading sessions, once with and once without Saige-Dx, with a washout period of at least 4 weeks in between the two sessions. The mammograms were collected from unique female patients 35 years of age or older according to an IRB approved protocol and were acquired from Hologic equipment. The cases in the study included 100 pathology-proven cancer cases and 140 confirmed non-cancer cases. To provide a mix of cancer cases that might be encountered in clinical practice, 67 of the cancer cases were recalled in clinical practice, indicating the interpreting radiologist detected a suspicion lesion and 33 of the cancer cases were not recalled in clinical practice, indicating the interpreting radiologist did not detect anything suspicious and the cancer was diagnosed at a later time. The patients in the study represented a racially and ethnically diverse population. Testing was also performed on a subgroup representative of the racial distribution of a United States screening population, which also met performance goals.

Each mammogram included in the study had one ground truth status: cancer or non-cancer. Two MQSA qualified, highly experienced (>10 years in practice) breast imaging specialists participated in establishing the reference standard for cancer and non-cancer exams. For each exam, the truthers confirmed and recorded the cancer status, as well as an interpretation of breast density. For cancer exams, the truthers annotated each malignant lesion on all views where the lesion was visible (based on the biopsied location that led to the malignant pathology) and indicated the lesion type. For exams where there were discrepancies between the two truther's assessment of density, lesion type, and/or lesion location, a third truther served as the adjudicator.

The reader performance increased with the aid of Saige-Dx from an average AUC of 0.865 when unaided to 0.925 when aided (difference of 0.06; 95% CI: 0.041, 0.079, p < 0.00001). All 18 readers demonstrated an increase in AUC performance when using Saige-Dx. The average reader sensitivity increased by 8.8% (95% CI: 7.0%, 10.6%). The average reader specificity increased by 0.9% (95% CI: -0.9%, 2.7%).

Similar reader performance trends were observed across breast densities, ages, race/ethnicities, lesion types and sizes, and radiologist specialization. For lesion type, the average AUC increased from 0.866 to 0.918 for soft tissue densities and from 0.795 to 0.899 for calcifications. For radiologist specialization, the average AUC for breast imaging specialists increased from 0.885 to 0.931 and from 0.826 to 0.911 for generalists.

Performance Testing: Standalone Study

A retrospective, blinded, multi-center study was conducted to evaluate the standalone performance of Saige-Dx on DBT mammograms. A total of 1304 cases were collected from 9 clinical sites in the United States, consisting of 136 cancer and 1168 non-cancer cases. The data was collected and truthed using similar procedures to those used for the reader study. All data came from clinical sites that had never been used previously for training or testing of the Saige-Dx AI algorithm. Saige-Dx exhibited an AUC of 0.930 (95% CI: 0.902, 0.958) on the dataset, demonstrating strong performance relative to the unaided reader performance in the reader study. Similar standalone performance trends were observed across breast densities, ages, race/ethnicities, and lesion types and sizes. Saige-Dx was assessed on both recalled and non-recalled cancers, as well as visible and non-visible cancers.

8. CONCLUSION

The non-clinical and clinical testing conducted to support this submission confirm that Saige-Dx is safe and effective. The minor differences, including technological differences, between Saige-Dx and the predicate do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. Therefore, the information presented in this 510(k) submission demonstrates that Saige-Dx is substantially equivalent to the predicate device.