



November 18, 2024

DeepHealth, Inc
B. Nathan Hunt
Head of Quality, Regulatory, and Compliance
212 Elm Street
Somerville, MA 02144

Re: K241747

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: October 18, 2024
Received: October 18, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

 Marjan Nabili -S for

Julie Sullivan, Ph.D.

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

Indications for Use

Submission Number (if known)

K241747

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K241747

**510(k) Summary
DeepHealth, Inc
Saige-Dx**

In accordance with 21 CFR 807.92 the following summary of information is provided, on this date, November 15, 2024:

1. 510(k) SUBMITTER

DeepHealth, Inc
212 Elm St.
Somerville, MA 02144
Tel: 443-506-8911

Contact Person:

B. Nathan Hunt
Head of Quality, Regulatory, and Compliance

DeepHealth, Inc.
212 Elm St
Somerville, MA 02144
Tel: 443-506-8911

Date Prepared:

November 15, 2024

2. DEVICE

Trade Name of Device:
Saige-Dx

Common or Usual Name:
Medical Image Software

Classification Names:
Radiological Computer Assisted Detection and Diagnosis Software(21 CFR 892.2090)

Regulation Class: II

Product Code: QDQ

3. PREDICATE DEVICE

Predicate Device:
Trade Name: Saige-Dx

Common or Usual Name:
Medical Image Software

Classification Names:
Radiological Computer Assisted Detection and Diagnosis Software (21 CFR 892.2090)

Regulation Class: II

Product Code: QDQ

510(K) No.: K220105

Device Models: v.2.0

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

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 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.

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 the same indications for use and patient population, and similar technical characteristics, and principles of operation. There are several minor differences between the subject device and the predicate device. Compared to the predicate device, the subject device now accepts DBT exams with unilateral images, exams from patients with breast implants that have implant displaced standard views, exams with Hologic HD images (1 mm slices and 6 mm slabs), and exams with GE images. The subject device also includes a new deployment option (Ephemeral mode), as well as upgrades to improve speed and memory use. The differences between the subject and predicate device do not alter the safety or effectiveness of the subject device for its intended use.

Both the subject and predicate 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 judgment. Both the subject and predicate devices are software systems that use artificial intelligence (AI)/machine learning algorithms that analyze mammography images to detect and characterize findings and provide information regarding the presence and location of the findings to the user.

Both devices are designed to fit in parallel to the standard-of-care workflow: mammography imaging studies are routed from the healthcare facility to the software device for processing, and after the analysis is completed, the results are sent back to the calling system to be displayed in the PACS or other worklist software.

The design of the current version of Saige-Dx is similar to that of the predicate device. 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

The design and development of Saige-Dx followed the following FDA recognized standards and guidance documents:

- ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices (#5-125)
- IEC 62304:2015 – Medical Device Software – Software Life Cycles Processes (#13-79)
- NEMA PS3 – Digital Imaging and Communications in Medicine (DICOM) Set (#12-300)
- Guidance for Industry and FDA Staff Content of Premarket Submission for Device Software Functions (June 2023)
- Guidance for Industry and FDA Staff: Software as a Medical Devices (SAMd): Clinical Evaluation (December 2017)

Saige-Dx is a software only device. Verification testing included software unit testing, software integration testing, system testing, and regression testing. Testing confirmed that the software, as designed and implemented, satisfied the software requirements and has no unintentional differences from the predicate device.

Training Dataset

The Saige-Dx algorithm was trained on a robust and diverse dataset of mammography exams

acquired from multiple vendors including GE and Hologic equipment. A total of nine datasets comprising 121,348 patients and 122,252 studies were collected from diverse practices with the majority from geographically diverse areas within the United States, including New York and California. The training dataset included age-appropriate and racially, ethnically, and socio-economically diverse populations. Aligned with good machine learning practices, a validation data usage plan was implemented ensuring no exam overlap between the training and testing datasets.

Performance Testing

Validation of the software was performed using standalone performance testing conducted under an approved IRB protocol. The testing dataset was an independent dataset which did not overlap with any of the data used for model development, training, or internal bench testing. The pivotal study compared the standalone performance between the predicate and the subject device. The primary endpoint was to demonstrate substantial equivalence of the subject device on compatible exams as compared to the performance of the predicate device on previously compatible exams, as defined as the lower bound of the 95% CI around the delta AUC between Hologic and GE cases as compared to Hologic only exams greater than the non-inferiority margin.

The reference standard for cancer and non-cancer exams were established by MQSA qualified, breast imaging specialists serving as truthers, including lesion localization for cancer exams. Briefly, each cancer exam and supporting medical reports were reviewed by two independent truthers, plus an additional adjudicator if needed.

The study endpoint was met which demonstrates that the standalone performance of the subject device is comparable and non-inferior to the performance of the predicate device). The case-level AUC on the compatible exams was 0.910 (0.886, 0.933). Performance testing concluded that the subject device met the pre-specified performance criteria.

The secondary assessment results further demonstrated that Saige-Dx has generalizable standalone performance on GE and Hologic exams across confounders such as patient age, breast density, breast size, race, ethnicity, exam type, lesion type, pathology classification, lesion size, and modality. Together these results support the safety and effectiveness of Saige-Dx on GE exams.

The standalone performance of the subject device was further tested on DBT screening mammograms with Hologic HD images, with unilateral breasts, and from patients with breast implants (on implant displaced views). All tests met the pre-specified performance criteria and the results support the safety and effectiveness of Saige-Dx on Hologic HD exams as well as exams with unilateral breasts and breast implants.

Testing Dataset

Mammograms were collected from unique female patients 35 years of age or older according to an IRB-approved protocol using standard imaging acquisition protocols for screening mammography. The dataset used for the evaluation of the Saige-Dx algorithm included screening DBT exams from 1,804 women with ages ranging from 35 to 89 (mean 59.2). All exams (236 cancer and 1,568 non-cancer) were acquired on Hologic and GE equipment and collected from 12 clinical sites across the United States. Cancer exams were confirmed to be malignant by biopsy pathology. Non-cancer exams were those without malignant biopsy pathology and confirmed by a negatively interpreted exam on the subsequent screen. Characteristics of the test set, i.e. age, race, ethnicity, breast density, breast size, imaging

modality, lesion size, lesion type, and lesion pathology classification confirmed that the test set is diverse and representative of the intended population for the intended use. In total, 63.6% of biopsy-proven cancer exams had soft tissue densities (architectural distortions, asymmetry, and/or mass), 17.4% had calcifications, and 19.1% had both. Of the cancer exams, 78% were invasive and 22% were non-invasive.

8. CONCLUSION

The testing conducted to support this submission confirms that Saige-Dx is safe and effective. The minor differences between the subject and predicate device 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.