June 15, 2026

DeepHealth, Inc.
Spence Hartwell
Principal, Regulatory Affairs
212 Elm St.
Somerville, Massachusetts 02144

Re: K253825
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 18, 2026
Received: May 19, 2026

Dear Spence Hartwell:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253825

Please provide the device trade name(s).

Saige-Dx

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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Somerville, MA 02144
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K253825
510(k) Summary
DeepHealth, Inc
Saige-Dx

In accordance with 21 CFR 807.92 the following summary of information is provided, on this date, June 12, 2026:

1. 510(k) SUBMITTER

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

Contact Person:

Spence Hartwell
Principal, Regulatory Affairs

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

Date Prepared:

June 12, 2026

2. DEVICE

Trade Name of Device:
Saige-Dx

Common or Usual Name:
Medical Image Software

Classification Names:
Radiological Computer Assisted Detection/Diagnosis Software for Lesions Suspicious for Cancer (21 CFR 892.2090)

Regulation Class: II

Product Code: QDQ

3. PREDICATE DEVICE

Predicate Device:

Trade Name: Saige-Dx

Device Model: v4.0.0

Common or Usual Name: Medical Image Software

Classification Names: Radiological Computer Assisted Detection/Diagnosis Software for Lesions Suspicious for Cancer (21 CFR 892.2090)

Regulation Class: II

Product Code: QDQ

510(K) No.: K251873

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 from a screening population 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. Compared to the predicate device, the subject device includes the capability to process prior exams which were validated on Hologic and GE mammography systems as a way to reduce the number of false positive marks per image (FPPI) by dropping false positive bounding boxes, by highlighting bounding boxes when a matching prior finding is identified, and by expanding the supported image view types. 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 subject device now supports an additional manufacturer (Siemens) to expand system compatibility.

The design of the current version of Saige-Dx is similar to that of the predicate device. Verification and Validation 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)
- Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005)
- 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.

Performance Testing

Saige-Dx was validated through two retrospective, blinded, pivotal standalone performance studies. The first assessed Siemens-acquired DBT screening mammograms, while the second evaluated using both current and prior screening exams from the same patients.

All testing datasets were independent and did not overlap with any data used for model development, training, or internal bench testing. The standalone performance of Saige-Dx was evaluated a dataset consisting of 2,425 Digital Breast Tomosynthesis DBT screening mammograms and the primary endpoint consisted in demonstrating non-inferior performance of the dataset with versus without Siemens data, calculated in terms of area under the curve (AUC). This dataset consisted of newly collected Siemens cases and a sub-sample of GE and Hologic DBT mammograms from the set of cases used in the pivotal study for FDA clearance (K251873). The priors dataset consisted of Hologic and GE mammograms collected under an IRB approved protocol. The dataset consisted of 684 patients for whom both a current and a prior DBT screening mammogram were available. The primary endpoint of the study was to demonstrate non-inferiority in performance, calculated in terms of AUC, sensitivity and specificity, with versus without priors. Table 1 shows the descriptive statistics of the datasets used in these evaluations.

Ground truth for each case was established to determine the reference standard cancer cases. All truthing radiologists were experienced breast imagers and blinded to AI outputs. Truthers confirmed cancer status and, for cancer cases, identified and localized all malignant lesions, documenting their pathology classification, lesion type, and location based on imaging, radiology reports, pathology reports, and other relevant clinical documentation.

Both studies met the pre-specified performance criteria, and the results support the safety and effectiveness for use on DBT exams acquired from Siemens systems and for incorporating prior screening exams. Additionally, subgroup analyses were performed as secondary assessments to demonstrate performance of the subject device across the intended use population and demonstrated similar standalone performance trends across breast densities, ages, race/ethnicities, manufacturers, lesion types and sizes.

Table 1. *Descriptive statistics of cases included in the Siemens Pivotal Standalone Study (n=2,425) and Priors Pivotal Standalone Study (n=684). Numbers in parentheses for Breast Density, Patient Race, and Patient Ethnicity are percentages. Numbers in parentheses for Patient Age are standard deviation (SD).*

	Siemens Pivotal Standalone Study All Cases (%)	**Priors Pivotal Standalone Study All Cases (%)**
Breast Density		
A	154 (6.4)	94 (13.7)
B	1090 (44.9)	399 (58.3)
C	1009 (41.6)	169 (24.7)
D	172 (7.1)	22 (3.2)
Patient Age		
Max	94.5	90.0
Mean (SD)	59.3 (10.9)	62.2 (10.9)
Min	35.2	39.0
Patient Ethnicity		
Hispanic/Latino	152 (6.3)	49 (7.2)
Not Hispanic/Latino	1748 (72.1)	492 (71.9)
Unknown	525 (21.6)	143 (20.9)

	Siemens Pivotal Standalone Study All Cases (%)	Priors Pivotal Standalone Study All Cases (%)
Patient Race		
American Indian/Alaska Native	8 (0.3)	5 (0.7)
Asian	116 (4.8)	44 (6.4)
Black/African American	751 (31.0)	74 (10.8)
Multiple	11 (0.5)	0 (0.0)
Native Hawaiian/Other Pacific Islander	4 (0.2)	1 (0.1)
Other	44 (1.8)	41 (6.0)
Unknown	467 (19.3)	4 (0.6)
White	1024 (42.2)	515 (75.3)
Manufacturer		
GE	514 (21.2)	304 (44.4)
Hologic	1402 (57.8)	380 (55.6)
Siemens	509 (21.0)	0 (0.0)
Exam Modality		
DBT + 2D synthetic	493 (20.3)	379 (55.4)
DBT + 2D synthetic + FFDM	1514 (62.4)	305 (44.6)
DBT + FFDM	418 (17.2)	0 (0.0)

8. CONCLUSION

Verification and Validation testing conducted to support this submission confirm that Saige-Dx is safe and effective. The 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.