December 19, 2024

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

Re: K243705
Trade/Device Name: Saige-Density (2.5.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: November 29, 2024
Received: November 29, 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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
Assistant Director
Mammograph 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243705

Device Name

Saige-Density (2.5.0)

Indications for Use *(Describe)*

Saige-Density is a software application intended for use with compatible full-field digital mammography (FFDM) and digital breast tomosynthesis (DBT) systems. Saige-Density provides an ACR BI-RADS Atlas 5th Edition breast density category to aid interpreting physicians in the assessment of breast tissue composition. Saige-Density produces adjunctive information. It is not a diagnostic aid.

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.

212 Elm St
Somerville, MA 02144
www.deephealth.com

510(k) Summary
DeepHealth, Inc
Saige-Density **K243705**

In accordance with 21 CFR 807.92 the following summary of information is provided, on this date, November 28, 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 28, 2024

1. DEVICE

Trade Name of Device: Saige-Density

Device Model: v.2.5.0

Common or Usual Name: Medical Image Software

Regulation Name and Number:
Medical Image Management and Processing System (21 CFR 892.2050)

Regulation Class: II

Product Code: QIH

2. PREDICATE DEVICE

Trade Name of Device: Saige-Density

Device Model: v2.0.0

Common Name or Usual Name: Medical Image Software

Regulation Name and Number:
Picture Archiving and Communication System (21 CFR 892.2050)

Regulation Class: II

3. DEVICE DESCRIPTION

Saige-Density is Software as a Medical Device that processes screening and diagnostic digital mammograms using deep learning techniques and generates outputs that serve as an aid for interpreting radiologists in assessing breast density. The software takes as input a single x-ray mammogram study and processes all acceptable 2D image DICOM files (FFDM and/or 2D synthetics) and generates a single study-level breast density category. Two DICOM files are outputted as a result: 1) a structured report (SR) DICOM object containing the case-level breast density category and 2) a secondary capture (SC) DICOM object containing a summary report with the study-level density category. Both output files contain the same breast density category ranging from “A” through “D” following Breast Imaging Reporting and Data System (BI-RADS) 5th Edition reporting guidelines. The SC report and/or the category in the SR file may be viewed on a mammography viewing workstation.

4. INDICATIONS FOR USE

Saige-Density is intended for use with compatible full-field digital mammography (FFDM) and digital breast tomosynthesis (DBT) systems. Saige-Density provides an ACR BI-RADS Atlas 5th Edition breast density category to aid interpreting physicians in the assessment of breast tissue composition. Saige-Density produces adjunctive information. It is not a diagnostic aid.

Intended User Population

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

Intended Patient Populations

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

Warnings and Precautions

Saige-Density 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-Density.

5. PREDICATE DEVICE COMPARISON

Saige-Density and the predicate device have the same indications for use, patient population, technical characteristics, and principles of operation. The differences between Saige-Density and the predicate device do not alter the suitability of the subject device for its intended use, and do not raise different questions of safety or effectiveness.

The devices are intended to be used by physicians to aid in the assessment of breast density for mammograms. The devices are not intended to be used as a replacement of a physician’s own clinical judgment.

The design of Saige-Density is similar to that of the predicate device. Both devices are compatible with FFDM and DBT mammograms, utilize deep learning to produce an output of a

patient-level breast density category, and are not diagnostic aids that are intended to be used by physicians interpreting either screening or diagnostic mammograms. As both devices use the same proprietary algorithm, there are no differences in the algorithmic components, only minor differences in the technological aspects. Compared to the predicate device, the subject device includes a new deployment option (single-execution mode), added consideration of deployment in a cloud-enabled environment, as well as upgrades to improve speed and memory use. Non-clinical and clinical testing has been completed as part of the prior K222275 submission ensuring the safety and effectiveness of the proposed subject device.

6. PERFORMANCE DATA

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 a retrospective study as described in K222275. The data used in the validation testing was obtained from different clinical sites than those used to develop the Saige-Density algorithm. DeepHealth ensured that there was no overlap between the data used to train and test the Saige-Density algorithm. The data used to train the Saige-Density algorithm consisted of four datasets across various geographic locations within the US, including racially diverse regions such as New York City and Los Angeles.

7. CONCLUSION

Verification and Validation testing conducted to support this submission confirm that Saige-Density is safe and effective for its intended use. The minor technological differences between subject and predicate versions of Saige-Density 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-Density is substantially equivalent to the predicate device.