December 16, 2022

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

Re: K222275
Trade/Device Name: Saige-Density
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: November 7, 2022
Received: November 7, 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); 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222275

Device Name
Saige-Density

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.

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

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Cambridge, MA 02138
Phone: 424-832-1480
www.deep.health

510(k) Summary
DeepHealth, Inc.
Saige-Density
(K222275)

In accordance with 21 CFR 807.92 the following summary of information is provided, on this date, December 15, 2022:

1. 510(k) SUBMITTER

DeepHealth, Inc.
1000 Massachusetts Avenue
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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
nhunt@deep.health

Date Prepared:

December 15, 2022

2. DEVICE

Trade Name of Device: Saige-Density

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

3. PREDICATE DEVICE

Trade Name: Densitas densityai™

Common Name or Usual Name: Medical Image Software

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

Regulation Class: II

Product Code: LLZ

510(K) No.: K192973

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4. 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.

5. 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.

6. PREDICATE DEVICE COMPARISON

Saige-Density and the predicate device have similar 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 equivalent main 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

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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-Density is a software device and has been determined to be 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 a retrospective study as described below. 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.

Standalone Performance Testing:

A multi-site retrospective study was conducted to evaluate the standalone performance of Saige-Density on DBT and FFDM mammograms. The primary objective was to quantify the accuracy of Saige-Density's density category outputs with respect to a consensus of five expert radiologists. The statistical analysis was performed by an independent biostatistician.

A total of 796 mammogram cases, representing 6,170 images, were retrospectively collected from five breast imaging centers in the United States. Importantly, the collection sites selected for the pivotal study did not overlap with those used previously to collect data for training or testing the Saige-Density AI algorithm. The cases were gathered from unique female patients 35 years of age or older and included different modalities (DBT and FFDM), manufacturers (Hologic and GE), and exam types (screening and diagnostic). Each mammogram included in the study had one ground truth status for density: A (Fatty), B (Scattered Fibroglandular), C (Heterogeneously Dense), or D (Extremely Dense) as defined by ACR's BI-RADS 5th Edition guidelines. Ground truth was established for each case as the consensus of five expert radiologists' breast density categories on the same set of cases, and calculated as the median of the reported categories for each case.

Saige-Density's accuracy was computed as the percentage of cases that Saige-Density assigned the same density category to as ground truth. Saige-Density's accuracy on four-class categorization (density categories A, B, C, or D) was 81.28% (95% CI: 78.42, 83.84). Results for four-class and two-class (nondense: A, B; dense: C,D) categorization with respect to ground truth are summarized in Figures 1 and 2, respectively.

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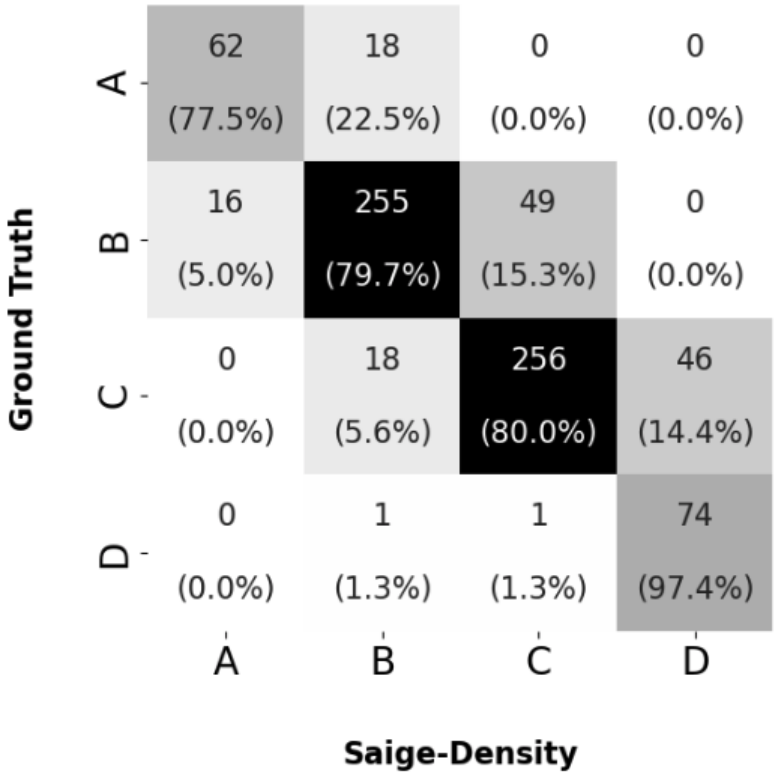

***Figure 1**. Four-class confusion matrix for all pivotal cases.*

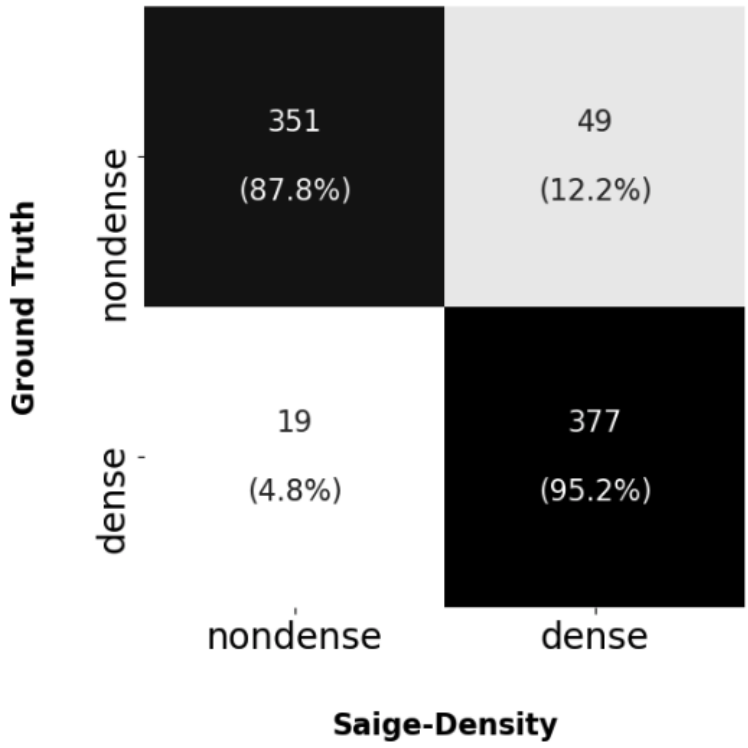

***Figure 2**. Two-class confusion matrix for all pivotal cases.*

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8. CONCLUSION

The non-clinical and clinical testing conducted to support this submission confirm that Saige-Density is safe and effective. The minor differences, including technological differences, between Saige-Density 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-Density is substantially equivalent to the predicate device.