



May 21, 2026

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

Re: K254131
Trade/Device Name: BAC
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: April 8, 2026
Received: April 8, 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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.

K254131

?

Please provide the device trade name(s).

?

BAC

Please provide your Indications for Use below.

?

BAC is intended to process screening mammograms to aid a qualified interpreting physician in the current manual process of identifying breast arterial calcifications.

BAC, a proprietary artificial intelligence (AI) based software device, is intended to detect, at the study and breast level, the presence or absence of breast arterial calcifications, an incidental finding in both Full Field Digital Mammogram (FFDM) and Digital Breast Tomosynthesis (DBT) screening mammograms. The device also provides localization information of detected breast arterial calcification on images.

The software device is intended to be used by qualified interpreting physicians in parallel with breast screening mammography workflow. The device is not intended for primary interpretation of digital mammography images as used for breast cancer detection. It should not be used alone to make any diagnosis and/or treatment decisions.

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

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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K254131
510(k) Summary
DeepHealth, Inc
BAC

In accordance with 21 CFR 807.92 the following summary of information is provided, on this date, May 20, 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:

May 20, 2026

2. DEVICE

Trade Name of Device:
BAC

Common or Usual Name:
Medical Image Software

Classification Names:
Medical Image Management and Processing System (21 CFR 892.2050)

Regulation Class: II

Product Code: QIH

3. PREDICATE DEVICE

Predicate Device:

Trade Name: cmAngio

Device Model: v1.6

Common or Usual Name:

Medical Image Software

Classification Names:

Medical Image Management and Processing System (21 CFR 892.2050)

Regulation Class: II

Product Code: QIH

510(K) No.: K250754

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

No reference devices were used in this submission.

4. DEVICE DESCRIPTION

BAC is a software device designed to be used by interpreting physicians during the review of full field digital mammography (FFDM) or digital breast tomosynthesis (DBT) exams. The device supports compatible FFDM or DBT systems to assist in identifying the presence or absence of breast arterial calcifications in mammograms.

The BAC software device is capable of detecting breast arterial calcifications on FFDM or DBT images. By indicating the presence or absence of breast arterial calcifications and localizing them within the mammography images, the device aids interpreting physicians in accurately reporting findings related to breast arterial calcifications.

5. INDICATIONS FOR USE

BAC is intended to process screening mammograms to aid a qualified interpreting physician in the current manual process of identifying breast arterial calcifications.

BAC, a proprietary artificial intelligence (AI) based software device, is intended to detect, at the study and breast level, the presence or absence of breast arterial calcifications, an incidental finding in both Full Field Digital Mammogram (FFDM) and Digital Breast Tomosynthesis (DBT) screening mammograms. The device also provides localization information of detected breast arterial calcification on images.

The software device is intended to be used by qualified interpreting physicians in parallel with breast screening mammography workflow. The device is not intended for primary interpretation of digital mammography images as used for breast cancer detection. It should not be used alone to make any diagnosis and/or treatment decisions.

Intended User Population

The intended users of this BAC software device are MQSA-qualified interpreting physicians in the United States who interpret mammograms to detect breast cancer.

Intended Patient Population

The software is intended for use on screening mammographic views of screening and diagnostic mammograms of female patients from a screening population.

Warnings and Precautions

BAC 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 BAC.

6. PREDICATE DEVICE COMPARISON

Both the subject and predicate devices are software systems that use artificial intelligence (AI)/machine learning algorithms to analyze mammography images and identify the presence or absence of breast arterial calcifications, as well as their location.

Both the subject and predicate devices take as input a single screening mammography exam (i.e., a mammogram of an asymptomatic woman). For both devices, the output consists of the result of AI model analysis, the presence and segmentation of BAC, or absence of BAC. Additionally, both devices have the same Clinical Output and Mode of Action.

Both the subject and predicate devices are designed to fit in parallel to the standard-of-care workflow: mammography imaging studies are routed from the healthcare facility's PACS 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 and predicate devices consist of substantially equivalent components performing comparable tasks. The specific organization and functioning of each component are also substantially equivalent between the two devices, and both consist of substantially equivalent components performing comparable tasks. Bench and clinical testing have been completed ensuring that the differences do not affect the safety and effectiveness of the proposed subject device.

The subject device includes a Predetermined Change Control Plan (PCCP). The authorized PCCP does not alter the indications for use nor the technological characteristics of the device (refer to Section 8). The PCCP for the proposed subject device does not raise different questions of safety and effectiveness from the predicate device.

7. PERFORMANCE DATA

The design and development of the device 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: 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)

BAC 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 BAC algorithm was trained on a robust and diverse dataset of mammography exams acquired from multiple clinical sites with diverse practices. 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 BAC software was conducted using a retrospective and blinded multicenter standalone performance study. The standalone performance of the subject device included testing on a total of 850 FFDM and 925 DBT images acquired from women presenting for bilateral screening mammograms. Cases were collected from 37 clinical sites in the United States, consisting of 150 (17.6%) BAC present and 700 (82.3%) BAC absent cases for FFDM and 169 (18.3%) BAC present and 756 (81.7%) BAC absent cases for DBT. Table 1 shows the descriptive statistics of the dataset used in this evaluation.

All testing datasets were independent and did not overlap with any data used for model development, training, or internal bench testing. Sensitivity and specificity for each modality met all pre-specified performance criteria: Sensitivity was 0.960 for FFDM and 0.905 for DBT, while specificity was 0.884 for FFDM and 0.906 for DBT. Collectively, the results supported the safety and effectiveness of the BAC device on DBT or FFDM exams. Accurate localization of breast arterial calcifications was also achieved. Additionally, subgroup analyses were performed as secondary assessments to demonstrate performance of the subject device across various subgroups and demonstrated similar standalone performance trends across breast densities, ages, and race/ethnicities.

Table 1. Descriptive statistics of cases included in BAC pivotal standalone performance study (n=850 for FFDM and n=925 for DBT), Numbers in parentheses for Breast Density, Patient Race, and Patient Ethnicity are percentages. Numbers in parentheses for Patient Age are standard deviation (SD).

	All Cases		BAC Present		BAC Absent	
	FFDM	DBT	FFDM	DBT	FFDM	DBT
Breast Density						
Non-Dense	426 (50.1)	473 (51.1)	97 (64.7)	114 (67.5)	329 (47.0)	359 (47.5)
Dense	424 (49.9)	452 (48.9)	53 (35.3)	55 (32.5)	371 (53.0)	397 (52.5)
Patient Age						
Mean (SD)	56.4 (11.8)	56.8 (11.7)	67.7 (10.6)	67.1 (10.4)	54.0 (10.5)	54.5 (10.7)
Min	26	26	41	40	26	26
Max	90	90	90	90	83	83
Patient Race						
American Indian/Alaskan Native	0 (0.0)	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.1)
Asian or Pacific Islander	2 (0.2)	10 (1.1)	2 (1.3)	4 (2.4)	0 (0.0)	6 (0.8)
Black or African American	50 (5.9)	82 (8.9)	14 (9.3)	22 (13.0)	36 (5.1)	60 (7.9)
White	55 (6.5)	83 (9.0)	10 (6.7)	21 (12.4)	45 (6.4)	62 (8.2)
Multiple	0 (0.0)	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.1)
Other	0 (0.0)	3 (0.3)	0 (0.0)	1 (0.6)	0 (0.0)	2 (0.3)
Unknown	743 (87.4)	745 (80.5)	124 (82.7)	121 (71.6)	619 (88.4)	624 (82.5)
Patient Ethnicity						
Hispanic or Latino	1 (0.1)	11 (1.2)	0 (0.0)	2 (1.2)	1 (0.1)	9 (1.2)
Not Hispanic or Latino	0 (0.0)	55 (6.0)	0 (0.0)	12 (7.1)	0 (0.0)	43 (5.7)
Unknown	849 (99.9)	859 (92.9)	150 (100.0)	155 (91.7)	699 (99.9)	704 (93.1)
Clinical Site Region						
Northeastern US	412 (48.5)	493 (53.3)	93 (62.0)	108 (63.9)	319 (45.6)	385 (50.9)
Southeastern US	114 (13.4)	119 (12.9)	26 (17.3)	31 (18.3)	88 (12.6)	88 (11.6)
Southwestern US	6 (0.7)	6 (0.7)	2 (1.3)	3 (1.8)	4 (0.6)	3 (0.4)
Western US	318 (37.4)	307 (33.2)	29 (19.3)	27 (16.0)	289 (41.3)	280 (37.0)

8. PREDETERMINED CHANGE CONTROL PLAN (PCCP)

The subject device includes a Predetermined Change Control Plan (PCCP). Two predetermined modifications are authorized with the PCCP:

1. Extend support to additional mammography image acquisition systems.
2. Update AI models to improve overall performance, enhance representation of clinically relevant subpopulations, or address performance drifts over time.

Modifications will be subject to validation prior to being implemented. The performance protocols used to test each modification are those used to clear the subject device without any changes to the acceptance criteria, such as sensitivity and specificity. The testing methods in those protocols engage standalone testing and paired analysis, when applicable. According to the PCCP, all performance requirements must be met prior to the modification being implemented. Mammography systems in scope include GE Senographe Essential and Senographe Pristina (FFDM and DBT), Siemens Mammomat Inspiration and Mammomat Revelation and Mammomat B. Brilliant (FFDM and DBT), and Fujifilm Aspire Cristalle (FFDM and DBT).

In accordance with the PCCP, the algorithm will be trained, tuned, and locked prior to commercial release of the algorithm with PCCP modifications. Updates to the device Instructions for Use (User Manual) will be made available and include performance information related to the PCCP modifications. The Instructions for Use will inform the user of all changes that are implemented after clearance of the subject device, including any modifications or extended support to any of the above mammography systems authorized with the PCCP.

The PCCP in the subject device with the proposed modifications related to extending supported FFDM/DBT image acquisition systems and updating AI models, does not raise different questions of safety and effectiveness from the predicate device.

9. CONCLUSION

Verification and Validation testing conducted to support this submission confirm that BAC 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 BAC is substantially equivalent to the predicate device.