April 1, 2026

Apple, Inc.
Lynda Ikejimba
Princ. Regulatory Affairs Assoc.
1 Apple Park Way
Cupertino, California 95014

Re: K253582
Trade/Device Name: Medical Imaging Calibration Feature (MICF)
Regulation Number: 21 CFR 892.1940
Regulation Name: Radiologic Quality Assurance Instrument
Regulatory Class: Class I
Product Code: SHN
Dated: March 2, 2026
Received: March 2, 2026

Dear Lynda Ikejimba:

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,

Catherine Olguin

For:

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
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.	K253582

Please provide the device trade name(s).

Medical Imaging Calibration Feature (MICF)

Please provide your Indications for Use below.

The Medical Imaging Calibration Feature (MICF) is a software-only medical device intended to calibrate compatible general purpose off-the-shelf (OTS) desktop displays. The MICF is intended to be used by trained medical practitioners for the purpose of enabling primary diagnostic interpretation and medical image review.

The MICF is intended to be used with specific macOS host and Apple display platforms. The MICF is not compatible with head-mounted displays, laptops, tablets, phones, or other portable displays that are not desktop displays. The device is not intended for mammography.

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)

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

1. Submitter

Applicant	Apple Inc. One Apple Park Way Cupertino, CA 95014
Submission Correspondent	Lynda Ikejimba, PhD Principal Regulatory Affairs Associate Phone: 650-695-9346 Email: Lc_ikejimba@apple.com
Secondary Correspondent	Sam Surette US Regulatory Affairs Manager Phone: 628-629-4161 Email: ssurette@apple.com
Date Prepared	March 27, 2026

2. Device Name and Classification

Subject Device:

Name of Device	Medical Imaging Calibration Feature (MICF)
Classification Name	Radiologic quality assurance instrument
Regulatory Class	21 CFR 892.1940
Product Code	SHN
510(k) Review Pannel	Radiology

3. Predicate Device

Radiologic quality assurance instrument, 21 CFR 892.1940.

4. Device Description

The Medical Imaging Calibration Feature (MICF) is a software-only device intended to calibrate a compatible general purpose off-the-shelf (OTS) Apple display to enable use of the display in primary diagnostic radiology. Specifically, the MICF is a Software as a Medical Device (SaMD), intended to provide adjustments to the display in accordance with the *Digital Imaging and Communications in Medicine* (*DICOM*) standard for medical imaging. As part of a clinical facility's quality assurance (QA) program, the MICF fulfills calibration and visual quality control (QC) testing of the radiologist's display. The MICF is intended to be used by trained medical practitioners authorized by their facility's QA program to perform display calibration.

5. Indications for Use

The Medical Imaging Calibration Feature (MICF) is a software-only medical device intended to calibrate compatible general purpose off-the-shelf (OTS) desktop displays. The MICF is intended to be used by trained medical practitioners for the purpose of enabling primary diagnostic interpretation and medical image review.

The MICF is intended to be used with specific macOS host and Apple display platforms. The MICF is not compatible with head-mounted displays, laptops, tablets, phones, or other portable displays that are not desktop displays. The device is not intended for mammography.

6. Comparison with the Predicate Device

The subject and predicate device, as described by the identification (21 CFR 892.1940), are both instruments used for radiologic QA. Technologically, the subject device is a software-only device intended to calibrate a compatible general purpose OTS desktop display via a connection with a compatible macOS general purpose computer and external third-party colorimeter. The predicate device also provides display calibration and has historically provided radiologic calibration and QC testing to other medical displays. The MICF can be used as part of a medical facility's QA program, consistent with the intended use of the predicate device. Since both the subject and predicate device (per 21 CFR 892.1940) are intended to enable use of a display for primary radiology, they have the same intended use.

While the MICF adjusts a general purpose OTS Apple display and the predicate provides calibration for a medical display, these technological differences do not raise different questions of safety or effectiveness, given that software devices that provide calibration are well characterized and have a known history of low risk. Furthermore, the differences in technological characteristics are addressed through acceptable scientific methods, from which the data demonstrate substantial equivalence.

The subject device has been appropriately verified and validated through non-clinical testing to ensure that the device is substantially equivalent to the predicate. A complete comparison of the subject and predicate devices can be found in **Table 1** below.

Table 1. MICF Comparison with the Predicate Device

Item	**Subject Device** Medical Imaging Calibration Feature (MICF)	**Predicate Device** 21 CFR 892.1940
Device Name	Medical Imaging Calibration Feature	N/A
Manufacturer	Apple, Inc.	N/A
Regulation Number	21 CFR 892.1940	21 CFR 892.1940
Product Code	SHN	N/A
Regulation Name	Radiologic quality assurance instrument	Radiologic quality assurance instrument
Regulation Subset	Display calibration software	Display calibration software
Device Classification	Class I	Class I
OTC/Prescription	Rx Only	Rx Only
Intended Use	Quality assurance device intended to calibrate a display to performance standards to enable use in primary diagnostic radiology.	Quality assurance device intended to calibrate a display to performance standards to enable use in primary diagnostic radiology.
Indications for Use	The Medical Imaging Calibration Feature (MICF) is a software-only medical device intended to calibrate compatible general purpose off-the-shelf (OTS) desktop displays. The MICF is intended to be used by trained medical practitioners for the purpose of enabling primary diagnostic interpretation and medical image review. The MICF is intended to be used with specific macOS host and Apple display platforms. The MICF is not compatible with head-mounted displays, laptops, tablets, phones, or other portable displays that are not desktop displays. The device is not intended for mammography.	N/A
Principle of Operation	Software-only medical device. Used with compatible OTS display, general purpose host computer, and external colorimeter.	Hardware and/or software medical device(s). Used with medical device displays, general purpose host computer, and external or internal colorimeter.
Use Environment	Anywhere primary diagnostic radiology is performed.	Anywhere primary diagnostic radiology is performed.

Item	**Subject Device** Medical Imaging Calibration Feature (MICF)	**Predicate Device** 21 CFR 892.1940
Intended Users	Qualified healthcare practitioners who have been authorized by their facility to use display calibration software.	Qualified healthcare practitioners who have been authorized by their facility to use display calibration software.
Display Performance	Tested in conformance with *DICOM*, *IEC 62563-1*, and *IEC 62563-2* standards for the purpose of enabling medical image review. Met acceptance criteria for primary radiology displays.	Tested in conformance with *DICOM*, *IEC 62563-1*, and *IEC 62563-2* standards for the purpose of enabling medical image review. Met acceptance criteria for primary radiology displays.
Display active screen size (diagonal)	Minimum 68 cm/ 27″	N/A
Display resolution	5120 x 2880 with no scaling	N/A
Display frame rate	47 - 120 Hz	N/A
Luminance (maximum, minimum, recommended)	Recommended: 600 nits (for TG-18) or 350 nits (for TG-270)	N/A
Color imaging	Yes	N/A
Gray imaging	Yes	Yes
DICOM calibration tool(s)	Internal calibration software External compatible colorimeter: Calibrite Display Plus HL Model Number CCDIS3PL	Internal calibration software, Internal/external colorimeter
Quality control procedures	AAPM TG-18 Compliant AAPM TG-270 Compliant	AAPM TG-18 Compliant AAPM TG-270 Compliant

The subject device and predicate devices shares the same intended use and represent the same generic device type as as established by 21 CFR 892.1940. While there are differences of technological characteristics, these differences do not raise different questions of safety and effectiveness. Data from acceptable methods, including results from software verification, hardware verification, and end-to-end physical bench validation testing substantiate the intended use of the subject device and demonstrate that the subject device is substantially equivalent to the predicate device. Thus, the MICF is substantially equivalent to the predicate device, radiologic quality assurance instrument (21 CFR 892.1940).

7. Summary of Non-Clinical Testing

Apple conducted non-clinical testing on the MICF with passing results, supporting a determination of substantial equivalence. Non-clinical testing included the following:

Software and Hardware Verification
As part of the software development life cycle, extensive software and hardware verification testing was conducted to asses the safe and effective use of the MICF with its supporting components. Software verification assessed if the software design was implemented and integrated per the integration plan (i.e. design outputs met design input requirements). Software verification assessed all code paths of the calibration algorithm, test and validation functions, and calibration reporting. Hardware verification assessed the interoperability of various macOS host platforms to support use of the MICF. Testing was conducted in accordance with with *IEC 82304-1 Health Software - General requirements for product safety* and *IEC 62304 Medical Device Software - Software life cycle process Edition 1.1 2015*. Pre-calibration testing was also conducted on the Apple display following recommendations in FDA's guidance document titled *Content of Premarket Submissions for Device Software Functions.* Results of verification testing demonstrated that the compatible Apple platforms supported use of the MICF, and that before MICF calibration the Apple display met technical requirements expected of displays used primary radiology.

Bench Validation Testing
The bench validation testing demonstrated that the MICF provides sufficient adjustments to the display in accordance with requirements for medical imaging use. Validation consisted of end-to-end physical testing of the calibrated display in accordance with *IEC 62563-1 Medical electrical equipment – Medical image display systems – Part 1: Evaluation methods*, *IEC 62563-2 Medical electrical equipment - Medical image display systems - Part 2: Acceptance and constancy tests for medical image displays*, and AAPM TG-18 and TG-270 technical practice parameters. The results validated that the medical calibration adjustments provided by MICF meet the technological tolerance requirements specified in *IEC 62563-2* and that the calibrated display meets the technical requirements necessary for use in primary diagnostic radiology. Furthermore, the results demonstrated that the MICF performs as intended when used in conjunction with an external colorimeter and that the general purpose computing platforms (i.e., Apple display) do not adversely affect the ability of the MICF to perform its calibration functions.

General Purpose Computing Platform Assessment
The MICF is a software-only device, available on the compatible macOS host and Apple display general purpose computing platforms. For this reason, medical device hardware testing is not applicable. However, as a multiple function device product, the potential impacts of the general purpose computing platforms on MICF functionality were assessed as part of the device's risk management, verification, and validation activities, and determined to be acceptable.

8. Summary of Clinical Testing

Clinical testing data was not submitted.

9. Conclusion

The Medical Imaging Calibration Feature is substantially equivalent to the predicate device as both devices share the same intended use, and where there are differences in technological characteristics the differences do not raise different questions of safety and effectiveness. Furthermore, the scientific methods used for evaluating the different technological characteristics of the subject device are acceptable. Results of the testing support a decision of substantial equivalence.