June 23, 2025

Apple Inc.
Ian Marcus
Regulatory Affairs
One Apple Park Way
Cupertino, CA 95014

Re: K250143
Trade/Device Name: Digital Prism Correction Feature (DPCF)
Regulation Number: 21 CFR 886.1655
Regulation Name: Ophthalmic Fresnel Prism
Regulatory Class: Class I
Product Code: SCW
Dated: May 19, 2025
Received: May 20, 2025

Dear Ian Marcus:

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).

As specified by 886.1655, this device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

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,

J Angelo Green -S

J. Angelo Green, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
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Center for Devices and Radiological Health

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)*

K250143

Device Name

Digital Prism Correction Feature (DPCF)

Indications for Use *(Describe)*

The Digital Prism Correction Feature (DPCF) is software that is intended to provide digital image adjustments in Apple Vision Pro in accordance with a user's prism prescription.

DPCF is available over-the-counter (OTC) for users with prism in their eyeglass prescription. When a prescription also includes other parts (e.g., sphere, cylinder, ADD), which can be fulfilled by optical inserts, the DPCF fulfills the prism part of the prescription while using Apple Vision Pro.

DPCF supports prism prescriptions up to 7.75 Prism Diopters (PD) in the horizontal and/or vertical dimension (i.e., base-up, base-down, base-in, base-out), per eye.

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.

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	Ian Marcus Regulatory Affairs Phone: 408-761-2934 Email: Ian_Marcus@apple.com
Secondary Correspondent	Sam Surette US Regulatory Affairs Manager Phone: 628-629-4161 Email: ssurette@apple.com
Date Prepared	January 17, 2025
Premarket Submission	Traditional 510(k)

2. Subject Device

510(k) Number	K250143
Name of Device	Digital Prism Correction Feature (DPCF)
Classification	Ophthalmic Fresnel prism, 21 CFR 886.1655
Regulatory Class	Class I
Product Code	SCW (Digital prismatic correction)
510(k) Review Panel	Ophthalmic

3. Predicate Device

510(k) Number	K240585
Name of Device	Digital Prism Correction Feature (DPCF)
Classification	Ophthalmic Fresnel prism, 21 CFR 886.1655
Regulatory Class	Class I

Product Code	SCW (Digital prismatic correction)
510(k) Review Panel	Ophthalmic

4. Device Description

The Digital Prism Correction Feature (DPCF) is intended to provide a high quality visual experience in Apple Vision Pro spatial computing applications for users with a prism prescription. Specifically, the DPCF is software that is intended to provide digital image adjustments in Apple Vision Pro in accordance with a user's prism prescription, in the horizontal and/or vertical dimensions. DPCF fulfills the prism part of an eyeglass prescription. When an eyeglass prescription also includes other parts (e.g., sphere, cylinder, ADD), DPCF fulfills the prism part of the prescription, while prescription optical inserts fulfill the other parts of the prescription.

The DPCF achieves its intended use by converting a user's prism prescription into digital image adjustment parameters that are utilized by the spatial computing image system to automatically provide digital image adjustments in horizontal and/or vertical dimensions in accordance with a user's prism prescription. At this time, DPCF supports prism prescriptions up to 7.75 Prism Diopters (PD) in the horizontal and/or vertical dimensions (i.e, base-up, base-down, base-in, base-out), per eye.

The DPCF is available over-the-counter (OTC).

5. Indications for Use

The Digital Prism Correction Feature (DPCF) is software that is intended to provide digital image adjustments in Apple Vision Pro in accordance with a user's prism prescription.

DPCF is available over-the-counter (OTC) for users with prism in their eyeglass prescription. When a prescription also includes other parts (e.g., sphere, cylinder, ADD), which can be fulfilled by optical inserts, the DPCF fulfills the prism part of the prescription while using Apple Vision Pro.

DPCF supports prism prescriptions up to 7.75 Prism Diopters (PD) in the horizontal and/or vertical dimensions (i.e., base-up, base-down, base-in, base-out), per eye.

6. Comparison with the Predicate Device

The subject device has the same technological characteristics and intended use as the predicate device (i.e., provides digital prismatic corrections in Apple Vision Pro). The subject device is indicated for over-the-counter (OTC) use, while the predicate is indicated for prescription use. The subject device's change to OTC use has been appropriately addressed to demonstrate that the subject device is substantially equivalent to the predicate device.

A complete comparison of the subject and predicate device can be found in **Table 1** below.

Table 1: DPCF Comparison with the Predicate

Item	**Subject Device** Digital Prism Correction Feature (DPCF)	**Predicate Device** K242058
Device Name	Digital Prism Correction Feature	Digital Prism Correction Feature
Manufacturer	Apple, Inc.	Apple, Inc.
Regulation Number	21 CFR 886.1655	21 CFR 886.1655
Product Code	SCW	SCW
Regulation Name	Ophthalmic Fresnel prism	Ophthalmic Fresnel prism
Device Classification	Class I	Class I
OTC/Prescription	OTC	Rx Only
Intended Use	Provide prismatic effect, and can be used in conjunction with lenses	Provide prismatic effect, and can be used in conjunction with lenses
Indications for Use	The Digital Prism Correction Feature (DPCF) is software that is intended to provide digital image adjustments in Apple Vision Pro in accordance with a user's prism prescription. DPCF is available over-the-counter (OTC) for users with prism in their eyeglass prescription. When a prescription also includes other parts (e.g., sphere, cylinder, ADD), which can be fulfilled by optical inserts, the DPCF fulfills the prism part of the prescription while using Apple Vision Pro. DPCF supports prism prescriptions up to 7.75 Prism Diopters (PD) in the horizontal and/or vertical dimension (i.e., base-up, base-down, base-in, base-out), per eye.	The Digital Prism Correction Feature (DPCF) is software that is intended to provide digital image adjustments in Apple Vision Pro in accordance with a user's prism prescription. DPCF is available for users with prism in their eyeglass prescription. When a prescription also includes other parts (e.g., sphere, cylinder, ADD), which can be fulfilled by optical inserts, the DPCF fulfills the prism part of the prescription while using Apple Vision Pro. DPCF supports prism prescriptions up to 7.75 Prism Diopters (PD) in the horizontal and/or vertical dimension (i.e., base-up, base-down, base-in, base-out), per eye.
Principle of Operation	Digital image adjustment in accordance with a prism prescription, to provide a prismatic effect.	Digital image adjustment in accordance with a prism prescription, to provide a prismatic effect.
Use Scenario(s)	Used with Apple Vision Pro, which can also include use in conjunction with optical inserts.	Used with Apple Vision Pro, which can also include use in conjunction with optical inserts.
Intended Users	Users in need of prism correction.	Users in need of prism correction.
Performance	Meets standardized prism tolerance requirements	Meets standardized prism tolerance requirements

7. Summary of Non-Clinical Testing

Human Factors and Usability Studies
Human Factors testing with 30 subjects was conducted to assess self-selection and use-related risks associated with use of the DPCF as an OTC device. The results of the human factors testing and Use-Related Risk Analysis (URRA) demonstrate that the use-related risks are acceptable and demonstrate substantial equivalence to the predicate device.

K242058 Non-Clinical Testing
Refer to K242058 for summary of additional previously submitted non-clinical testing, including bench validation testing that demonstrated DPCF meets prism tolerance requirements specified in ISO 8980-1:2017.

8. Summary of Clinical Testing

No clinical testing data has been submitted.

9. Conclusion

The Digital Prism Correction Feature (DPCF) indicated for over-the-counter (OTC) use is substantially equivalent to the predicate device. OTC use does not represent a different intended use that raises different questions of safety and effectiveness, nor does it significantly affect the safety or effectiveness of the device. Since the subject and predicate device have the same intended use, and there are no differences in technological characteristics, the subject device is substantially equivalent to the predicate device.