October 21, 2024

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

Re: K242058
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: July 12, 2024
Received: September 10, 2024

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).

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,

J Angelo Green -S

J. Angelo Green, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices
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.

510(k) Number *(if known)*
K242058

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 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.

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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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	July 12, 2024
Premarket Submission	Traditional 510(k), K242058

2. Device Names and Classifications

Subject Device:

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

Ophthalmic Fresnel prism, 21 CFR 886.1655.

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.

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 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 and predicate device, as described by the identification (21 CFR 886.1655), are both intended to provide a prismatic effect. The subject device provides a prismatic effect by providing perceived digital image shift in horizontal and/or vertical dimensions in accordance with a user's prescription; the predicate device also provides perceived prismatic effects. Furthermore, the DPCF can be used in conjunction with ophthalmic lenses, consistent with the intended use of the predicate device, for which the classification's identification describes a device that can be applied to lenses. Since both the subject and predicate device (per 21 CFR 886.1655) are intended to provide prismatic effects in accordance with a prism prescription, and can be used in conjunction with spectacle lenses, they have the same intended use.

While DPCF prismatically adjusts a digital image using software, and the predicate provides a prismatic effect through a plastic sheet adhered to lenses, these technological differences do not raise different questions of safety or effectiveness, given that devices that provide prismatic effects are well characterized and have a known history of very 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 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** 21 CFR 886.1655
Device Name	Digital Prism Correction Feature	N/A
Manufacturer	Apple, Inc.	N/A
Regulation Number	21 CFR 886.1655	21 CFR 886.1655
Product Code	SCW	HKT
Regulation Name	Ophthalmic Fresnel prism	Ophthalmic Fresnel prism
Device Classification	Class I	Class I
OTC/Prescription	Rx Only	N/A
Intended Use	Provide prismatic effect, and can be used in conjunction with lenses	Provide prismatic effect, and are 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 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.	N/A
Principle of Operation	Digital image adjustment in accordance with a prism prescription, to provide a prismatic effect.	Optical refraction 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 in conjunction with spectacle lenses
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

The subject device shares the same intended use and represents the same generic device type as the predicate device, as established by 21 CFR 886.1655. While there are differences of technological characteristics, these differences do not raise different questions of safety and effectiveness. Data from acceptable methods have been provided in this 510(k) submission, including results from bench validation testing, to substantiate the intended use of the subject device and demonstrate the subject device is substantially equivalent to the predicate device. The differences between the subject and predicate device do not present any new issues of safety or effectiveness as they do not increase the risk of the device, and can be appropriately verified and validated through existing methods. Thus, the DPCF is substantially equivalent to the predicate device, ophthalmic Fresnel prism (21 CFR 886.1655).

7. Summary of Non-Clinical Testing

Non-clinical Testing Summary

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

Software Verification and Validation
Software verification and validation was conducted in accordance with Apple's robust quality system and documented to address the recommendations in FDA's "Content of Premarket Submissions for Device Software Functions" guidance document. DPCF was determined to be a Basic Documentation Level. Apple's good software engineering practices, as demonstrated by the 510(k) submission's documentation, supports a conclusion that DPCF was appropriately designed, verified, and validated.

Bench Validation Testing
The bench validation testing demonstrated that the DPCF provides prismatic adjustments in accordance with a prism prescription. Specifically, the results validate that the digital image adjustments provided by DPCF meet the prism tolerance requirements specified in ISO 8980-1:2017, and demonstrates that the DPCF provides reliable and acceptable prism adjustments for the available prism adjustment range, including for both virtual and digital pass-through content. Furthermore, the results demonstrate that the DPCF performs as intended with and without optical inserts, and that the general purpose spatial computing platform (i.e., Apple Vision Pro) and it's "other functions" do not adversely affect the DPCF's ability to meet standardized prism tolerances.

General Purpose Spatial Computing Platform Assessment
DPCF is a software-only device, available on compatible general purpose spatial computing platforms (i.e., Apple Vision Pro); therefore, medical device hardware testing is not applicable. However, as a multiple function device product, the impact of the general purpose spatial computing platform on DPCF was assessed as part of the feature's risk management, verification, and validation activities, and determined to be acceptable.

8. Summary of Clinical Testing

No clinical testing data has been submitted.

9. Conclusion

The Digital Prism Correction Feature is substantially equivalent to the predicate device as they share the same intended use and where there are differences in technological characteristics, these 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 and the results of that testing supports a decision of substantial equivalence.