FDA 510(k) Premarket Notification

# K242058 Digital Prism Correction Feature (DPCF)

**CLEARED**

Oct 21, 2024
98 days to decision

K242058 · Product code: **SCW** · Ophthalmic
Source: https://www.510kdatabase.net/k242058/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Digital Prismatic Correction (SCW) |
| Date received | Jul 15, 2024 |
| Decision date | Oct 21, 2024 |
| Days to decision | 98 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Apple, Inc.** |
| Location | Alexandria, VA, US |
| Contact | Ian Marcus |
| Website | http://www.apple.com/it/ |
| 510(k) history | 12 submissions · 9 cleared · 2018-2026 |

Apple, Inc. is a technology company that develops consumer electronics and digital health solutions. The company operates with a manufacturing facility in Alexandria, US, and has expanded into medical device development through FDA-regulated health features integrated into its consumer products. Apple has received FDA 510(k) clearances from total submissions since its first clearance in 2018. The company's cleared devices focus primarily on cardiovascular monitoring and ophthalmic applications, with recent clearances including notification features for hypertension, irreg...