FDA 510(k) Premarket Notification

K250143 Digital Prism Correction Feature (DPCF)

CLEARED

Jun 23, 2025
157 days to decision

K250143 · Product code: **SCW** · Ophthalmic
Source: https://www.510kdatabase.net/k250143/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Digital Prismatic Correction (SCW)
Date received	Jan 17, 2025
Decision date	Jun 23, 2025
Days to decision	157 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...