

K253582 Medical Imaging Calibration Feature (MICF)Apr 1, 2026
135 days to decisionK253582 · Product code: **SHN** · Radiology
Source: <https://www.510kdatabase.net/k253582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Nov 17, 2025
Decision date	Apr 1, 2026
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Apple, Inc.
Location	Alexandria, VA, US
Contact	Lynda Ikejimba
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...
