

**K231173 Irregular Rhythm Notification Feature (IRNF)**Jul 21, 2023  
87 days to decisionK231173 · Product code: **QDB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k231173/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Photoplethysmograph Analysis Software For Over-the-counter Use (QDB)
Date received	Apr 25, 2023
Decision date	Jul 21, 2023
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Apple, Inc.</b>
Location	Alexandria, VA, US
Contact	Bonnie Wu
Website	<a href="http://www.apple.com/it/">http://www.apple.com/it/</a>
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...

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