FDA 510(k) Premarket Notification

# K212516 IRNF App

**CLEARED**

Oct 22, 2021
73 days to decision

K212516 · Product code: **QDB** · Cardiovascular
Source: https://www.510kdatabase.net/k212516/

**SUBMISSION DETAILS**

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Photoplethysmograph Analysis Software For Over-the-counter Use (QDB) |
| Date received | Aug 10, 2021 |
| Decision date | Oct 22, 2021 |
| Days to decision | 73 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

**APPLICANT**

| | |
|---|---|
| Company | **Apple, Inc.** |
| Location | Alexandria, VA, US |
| Contact | Dachan Kwon |
| 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...

**CLINICAL EVIDENCE - NCT04699812**

### Atrial Fibrillation Algorithms Clinical Validation Study

| | |
|---|---|
| Status | Completed |
| Enrollment | 573 patients (actual) |
| Study sites | 4 sites |
| Condition studied | Atrial Fibrillation |
| Primary purpose | Screening |
| Study type | Interventional |
| Study design | Parallel |
| Masking | Open label |
| Completion date | Dec 17, 2021 |
| Sponsor | Apple Inc. (Industry) |

**Primary outcome**

SENSITIVITY OF IRREGULAR RHYTHM NOTIFICATION FEATURE [IRNF]

**Secondary outcome**

POSITIVE PREDICTIVE VALUE OF IRREGULAR RHYTHM NOTIFICATION FEATURE [IRNF]

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04699812