FDA 510(k) Premarket Notification

CLEARED

K240929 Sleep Apnea Notification Feature (SANF)

Sep 13, 2024
162 days to decision

K240929 · Product code: **QZW** · Anesthesiology
Source: https://www.510kdatabase.net/k240929/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Device To Assess Risk Of Sleep Apnea (QZW)
Date received	Apr 4, 2024
Decision date	Sep 13, 2024
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
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...