FDA 510(k) Premarket Notification

K261011 Sleep Apnea Feature (v2.0)

CLEARED

Jul 20, 2026
116 days to decision

K261011 · Product code: **QZW** · Anesthesiology
Source: https://www.510kdatabase.net/k261011/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Device To Assess Risk Of Sleep Apnea (QZW)
Date received	Mar 26, 2026
Decision date	Jul 20, 2026
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	**Samsung Electronics Co., Ltd.**
Location	Echo, OR, US
Contact	Hon Pak
Website	http://www.samsung.com
510(k) history	42 submissions · 41 cleared · 2013-2026

Samsung Electronics Co., Ltd. is a South Korean multinational electronics corporation headquartered in Suwon. The company maintains a regulatory presence in the United States through its Echo, US location. Samsung has submitted total applications for FDA 510(k) clearance and received clearances. The company's regulatory focus centers on Radiology devices, which represent 83% of submissions. Samsung's FDA 510(k) clearance history spans from 2013 to 2024, with recent clearances demonstrating continued regulatory activity in medical imaging and cardiovascular monitoring tech...

REGULATORY CONSULTANT

Consulting firm	**Samsung Research America, Inc.**
Contact	Chaoyi Kang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov