

K261187 Hearing Aid Feature

Jul 31, 2026
112 days to decision

K261187 · Product code: **SCR** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k261187/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Air-conduction Hearing Aid Software (SCR)
Date received	Apr 10, 2026
Decision date	Jul 31, 2026
Days to decision	112 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](https://accessdata.fda.gov)

CLINICAL EVIDENCE - NCT07020663

[Trial of device that is not approved or cleared by the U.S. FDA]

Status	Withheld - <i>No results published to ClinicalTrials.gov</i>
Sponsor	[Redacted]

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT07020663