

K261519 Sonio Suspect

Jun 4, 2026
28 days to decision

K261519 · Product code: **POK** · Radiology
Source: <https://www.510kdatabase.net/k261519/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	May 7, 2026
Decision date	Jun 4, 2026
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sonio
Location	Paris, FR
Contact	Florian Akpakpa
510(k) history	5 submissions · 5 cleared · 2023-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k261519/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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