

K243614 Sonio Suspect

Feb 21, 2025
91 days to decision

K243614 · Product code: **POK** · Radiology
Source: <https://www.510kdatabase.net/k243614/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Nov 22, 2024
Decision date	Feb 21, 2025
Days to decision	91 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	4 submissions · 4 cleared · 2023-2026
