

K251071 Fetal EchoScan (v1.1)

May 2, 2025
25 days to decision

K251071 · Product code: **POK** · Radiology
Source: <https://www.510kdatabase.net/k251071/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Apr 7, 2025
Decision date	May 2, 2025
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Brighthouse
Location	Paris, FR
Contact	Christophe Gardella
510(k) history	5 submissions · 5 cleared · 2024-2025
