

K242342 Fetal EchoScanNov 14, 2024
99 days to decisionK242342 · Product code: **POK** · Radiology
Source: <https://www.510kdatabase.net/k242342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Aug 7, 2024
Decision date	Nov 14, 2024
Days to decision	99 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242342/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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