

**K252294 Fetal EchoScan (v1.2)**Dec 8, 2025  
138 days to decisionK252294 · Product code: **POK** · Radiology  
Source: <https://www.510kdatabase.net/k252294/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Jul 23, 2025
Decision date	Dec 8, 2025
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252294/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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