FDA 510(k) Premarket Notification

K252294 Fetal EchoScan (v1.2)

CLEARED

Dec 8, 2025
138 days to decision

K252294 · Product code: **POK** · Radiology
Source: https://www.510kdatabase.net/k252294/

SUBMISSION DETAILS

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

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