FDA 510(k) Premarket Notification

K242342 Fetal EchoScan

CLEARED

Nov 14, 2024
99 days to decision

K242342 · 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	**Brightheart**
Location	Paris, FR
Contact	Christophe Gardella
510(k) history	5 submissions · 5 cleared · 2024-2025