

K241380 FETOLY-HEARTSep 11, 2024
119 days to decisionK241380 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k241380/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 15, 2024
Decision date	Sep 11, 2024
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diagnoly
Location	Lyon, FR
Contact	Ivan Voznyuk
510(k) history	2 submissions · 2 cleared · 2024-2025

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