

K242321 KosmosApr 25, 2025
262 days to decisionK242321 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k242321/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 6, 2024
Decision date	Apr 25, 2025
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	EchoNous, Inc.
Location	Redmond, VA, US
Contact	Joshua Kim
510(k) history	5 submissions · 5 cleared · 2018-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242321/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026