

K212100 KosmosAug 6, 2021
31 days to decisionK212100 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k212100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 6, 2021
Decision date	Aug 6, 2021
Days to decision	31 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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