

K250959 BioticsAIDec 22, 2025
266 days to decisionK250959 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k250959/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 31, 2025
Decision date	Dec 22, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bioticsai, Inc.
Location	Brentwood, CA, US
Contact	Salman Khan
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Innolitics, LLC
Contact	Meri Martinez

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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