FDA 510(k) Premarket Notification

K243227 B-Scan

CLEARED

Jul 11, 2025
276 days to decision

K243227 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k243227/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Oct 8, 2024
Decision date	Jul 11, 2025
Days to decision	276 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Accutome, Inc. Doing Business AS Keeler USA**
Location	Malvern, PA, US
Contact	Claudia Hill
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Keeler, Ltd.**
Contact	Sonia Bargotta

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