

K250331 Astrasono A3Pro Bladder Scanner (A3Pro)Sep 30, 2025
237 days to decisionK250331 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k250331/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Feb 5, 2025
Decision date	Sep 30, 2025
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Astrasono Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Charles Shen
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Manton Business and Technology Services
Contact	Charles Shen

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

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