

K253898 QT Scanner 2000 Model AMar 4, 2026
89 days to decisionK253898 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k253898/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Dec 5, 2025
Decision date	Mar 4, 2026
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	QT Imaging Holdings, Inc.
Location	Novato, CA, US
Contact	Bilal Malik
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253898/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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