

K213620 ATUSA™ Automated 3D Breast Ultrasound SystemApr 22, 2022
157 days to decisionK213620 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k213620/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Nov 16, 2021
Decision date	Apr 22, 2022
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Isono Health, Inc.
Location	South San Francisco, CA, US
Contact	Shadi Saberi
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Compliance and Regulatory Services, LLC
Contact	Daniel Lehtonen

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

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