FDA 510(k) Premarket Notification

CLEARED

K230511 K3900 Ultrasound Imaging System

Oct 25, 2023
243 days to decision

K230511 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k230511/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Feb 24, 2023
Decision date	Oct 25, 2023
Days to decision	243 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Maui Imaging**
Location	Bellevue, WA, US
Contact	David Specht
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Mdqr, LLC**
Contact	Prabhu Raghavan

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