

K213254 Axialis Ophthalmic Ultrasound SystemNov 15, 2021
46 days to decisionK213254 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k213254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Sep 30, 2021
Decision date	Nov 15, 2021
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Quantel Medical
Location	Cournon D'auvergne-Cedex, FR
Contact	Bruno Pages
Website	https://www.quantelmedical.com
510(k) history	30 submissions · 30 cleared · 2000-2026

REGULATORY CONSULTANT

Consulting firm	O'Connell Regulatory Consultants, Inc.
Contact	Maureen O'Connell

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

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