FDA 510(k) Premarket Notification

K232302 Pocket III

CLEARED

Apr 26, 2024
269 days to decision

K232302 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k232302/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 1, 2023
Decision date	Apr 26, 2024
Days to decision	269 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