FDA 510(k) Premarket Notification

K211529 NAVIRFA Scope

CLEARED

May 5, 2022
353 days to decision

K211529 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k211529/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	May 17, 2021
Decision date	May 5, 2022
Days to decision	353 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Navifus Corporation**
Location	Datong Dist., Taipei City, TW
Contact	Arthur Lung
510(k) history	1 submissions · 1 cleared · 2022-2022