FDA 510(k) Premarket Notification

CLEARED

K250592 NES Reprocessed Visions PV .018 Digital IVUS Catheter (R-86700)

May 12, 2025
74 days to decision

K250592 · Product code: **OWQ** · Cardiovascular
Source: https://www.510kdatabase.net/k250592/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Feb 27, 2025
Decision date	May 12, 2025
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Northeast Scientific, Inc.**
Location	Waterbury, CT, US
Contact	Matthew Farley
510(k) history	6 submissions · 6 cleared · 2007-2025