

**K223026 NES Reprocessed Eagle Eye Platinum RX Digital IVUS Catheter**Feb 3, 2023  
127 days to decisionK223026 · Product code: **OWQ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k223026/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Sep 29, 2022
Decision date	Feb 3, 2023
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Northeast Scientific, Inc.</b>
Location	Waterbury, CT, US
Contact	Matt Farley
510(k) history	6 submissions · 6 cleared · 2007-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223026/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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