

**K200195 NES Reprocessed Visions PV .014P RX Digital IVUS Catheter**Jun 22, 2020  
147 days to decisionK200195 · Product code: **OBJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k200195/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Jan 27, 2020
Decision date	Jun 22, 2020
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Northeast Scientific, Inc.</b>
Location	Waterbury, CT, US
Contact	Matthew 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/k200195/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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