

**K230584 Vein360 Reprocessed Visions PV.035 Digital IVUS Catheter**Jun 6, 2023  
96 days to decisionK230584 · Product code: **OWQ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k230584/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Mar 2, 2023
Decision date	Jun 6, 2023
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vein 360, LLC</b>
Location	Blue Ash, OH, US
Contact	Suzanne Meyer
510(k) history	4 submissions · 4 cleared · 2019-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230584/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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