

**K232584 Vein360 Reprocessed Visions PV.014P Rx Digital IVUS Catheter, Vein360 Reprocessed Eagle Eye Platinum Rx Digital IVUS Catheter, Vein360 Reprocessed Eagle Eye Platinum ST Rx Digital IVUS Catheter**Oct 24, 2023  
60 days to decisionK232584 · Product code: **OWQ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k232584/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Aug 25, 2023
Decision date	Oct 24, 2023
Days to decision	60 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/k232584/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 26, 2026