

K230928 Vein360 Reprocessed Visions PV.018 Digital IVUS CatheterAug 25, 2023
144 days to decisionK230928 · Product code: **OWQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k230928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Apr 3, 2023
Decision date	Aug 25, 2023
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230928/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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