CLEARED

Oct 24, 2023
60 days to decision

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

K232584 · Product code: **OWQ** · Cardiovascular
Source: https://www.510kdatabase.net/k232584/

SUBMISSION DETAILS

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

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