FDA 510(k) Premarket Notification

CLEARED

K230584 Vein360 Reprocessed Visions PV.035 Digital IVUS Catheter

Jun 6, 2023
96 days to decision

K230584 · Product code: **OWQ** · Cardiovascular
Source: https://www.510kdatabase.net/k230584/

SUBMISSION DETAILS

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

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