

K201085 NeVa PV Thrombectomy DeviceJan 15, 2021
267 days to decisionK201085 · Product code: **QEW** · CardiovascularSource: <https://www.510kdatabase.net/k201085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Apr 23, 2020
Decision date	Jan 15, 2021
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vesalio
Location	Nashville, TN, US
Contact	Gustavo Prado
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Biologics and Medical Device Consulting Group
Contact	Sigi Caron

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201085/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026