FDA 510(k) Premarket Notification

CLEARED

K182167 The ICHOR Panacea Vascular Embolectomy Catheter System

Dec 21, 2018
133 days to decision

K182167 · Product code: **QEW** · Cardiovascular
Source: https://www.510kdatabase.net/k182167/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Aug 10, 2018
Decision date	Dec 21, 2018
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ichor Vascular, Inc.**
Location	Toledo, OH, US
Contact	Jeff Blair
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	**Namsa**
Contact	Angela Mallery

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov