FDA 510(k) Premarket Notification

CLEARED

K243105 Ruby Intravascular Catheter

May 16, 2025
228 days to decision

K243105 · Product code: **FOZ** · General Hospital
Source: https://www.510kdatabase.net/k243105/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Sep 30, 2024
Decision date	May 16, 2025
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Venocare, Inc.**
Location	Doral, FL, US
Contact	Raul Leyte-Vidal
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Daniel & Daniel, LLC**
Contact	Mark Smutka

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