FDA 510(k) Premarket Notification

CLEARED

K254022 FLASH Flex™ Aorto-Ostial Angioplasty System

Apr 2, 2026
107 days to decision

K254022 · Product code: **LOX** · Cardiovascular
Source: https://www.510kdatabase.net/k254022/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Dec 16, 2025
Decision date	Apr 2, 2026
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Verge Medical, Inc.**
Location	Campbell, CA, US
Contact	Michael Buck
510(k) history	2 submissions · 2 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Bridge City Regulatory, LLC**
Contact	Reynier Jacinto

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