

**K254022 FLASH Flex™ Aorto-Ostial Angioplasty System**Apr 2, 2026  
107 days to decisionK254022 · Product code: **LOX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k254022/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Bridge City Regulatory, LLC</b>
Contact	Reynier Jacinto

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k254022/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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