

K161967 FluidiTube 2.7F Infusion Micro Catheter, 110 cm and 130 cmJan 27, 2017
193 days to decisionK161967 · Product code: **KRA** · Cardiovascular
Source: <https://www.510kdatabase.net/k161967/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Continuous Flush (KRA)
Date received	Jul 18, 2016
Decision date	Jan 27, 2017
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Callisyn Biomedical, Inc.
Location	North Andover, MA, US
Contact	Shallwei Sun
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161967/>. 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 June 1, 2026