FDA 510(k) Premarket Notification

CLEARED

K254089 IOPS Visionary System (MC-3)

Feb 17, 2026
60 days to decision

K254089 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k254089/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 19, 2025
Decision date	Feb 17, 2026
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	IOPS Viewpoint Simple Curve Catheter, 75cm (C00751); IOPS Viewpoint Simple Curve Catheter, 125cm (C01251); IOPS Viewpoint Double Curve Catheter, 75cm (C00752); IOPS Viewpoint Double Curve Catheter, 125cm (C02152); IOPS Guidewire 2 (ATW-2); IOPS Fiducial Tracking Pad (T02111); IOPS Guidewire Handle (H01035)

APPLICANT

Company	**Centerline Biomedical, Inc.**
Location	Cleveland, OH, US
Contact	Carroll Martin
Website	https://centerlinebiomedical.com
510(k) history	6 submissions · 6 cleared · 2019-2026

Centerline Biomedical, Inc. develops FDA-cleared endovascular navigation technology with a manufacturing facility in Cleveland, US. The company specializes in Cardiovascular devices designed to reduce radiation exposure and improve procedural accuracy during interventional procedures. Centerline Biomedical has received FDA 510(k) clearances from total submissions since its first clearance in 2019. The company remains active, with its most recent clearance in 2026. All submissions focus on Cardiovascular devices, reflecting the company's core expertise in intra-operative p...