FDA 510(k) Premarket Notification

K261329 Intra-Operative Positioning System (IOPS) (MC-1)

CLEARED

Jun 10, 2026
49 days to decision

K261329 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k261329/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Apr 22, 2026
Decision date	Jun 10, 2026
Days to decision	49 days
Third-party review	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**
Location	Warrensville Heights, OH, US
Contact	Carroll Martin
510(k) history	1 submissions · 1 cleared · 2026-2026