FDA 510(k) Premarket Notification

CLEARED

K230309 Intra-Operative Positioning System (IOPS®) (MC-1)

Jun 21, 2023
138 days to decision

K230309 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k230309/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Feb 3, 2023
Decision date	Jun 21, 2023
Days to decision	138 days
Third-party review	No
Summary / Statement	Summary
Other names	IOPS Simple Curve Catheter (SCC-1) and IOPS Reverse Curve Catheter (RCC-1); IOPS Guidewire (ATW-2); IOPS Tracking Pad (TP-1); IOPS Guidewire Handle (SSH-1)

APPLICANT

Company	**Centerline Biomedical, Inc.**
Location	Cleveland, OH, US
Contact	Amanda Shade
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...