FDA 510(k) Premarket Notification

CLEARED

K190106 Intra-Operative Positioning System

Jun 24, 2019
153 days to decision

K190106 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k190106/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jan 22, 2019
Decision date	Jun 24, 2019
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary
Other names	Simple Curve Catheter, Reverse Curve Catheter ; Angled Tip Guidewire ; Tracking Pad ; Guidewire Handle

APPLICANT

Company	**Centerline Biomedical, Inc.**
Location	Cleveland, OH, US
Contact	Vikash Goel
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...