FDA 510(k) Premarket Notification

CLEARED

K243842 Intra-Operative Positioning System (IOPS®)

Mar 6, 2025
83 days to decision

K243842 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k243842/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 13, 2024
Decision date	Mar 6, 2025
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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...