FDA 510(k) Premarket Notification

K251668 SurfRider 13 Microcatheter

CLEARED

Jan 5, 2026
220 days to decision

K251668 · Product code: **QJP** · Neurology
Source: https://www.510kdatabase.net/k251668/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	May 30, 2025
Decision date	Jan 5, 2026
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Kaneka Americas Holding, Inc.**
Location	Newark, CA, US
Contact	Takuji Nishide
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Mededge**
Contact	Darci Diage

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov