FDA 510(k) Premarket Notification

K214025 PROWLER SELECT LP ES Microcatheter

CLEARED

Apr 12, 2022
111 days to decision

K214025 · Product code: **KRA** · Neurology
Source: https://www.510kdatabase.net/k214025/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Continuous Flush (KRA)
Date received	Dec 22, 2021
Decision date	Apr 12, 2022
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	PROWLER XS Microcatheter

APPLICANT

Company	**Medos International SARL**
Location	Raynham, MA, US
Contact	Ivenette Guzman
510(k) history	96 submissions · 96 cleared · 2010-2026

REGULATORY CONSULTANT

Consulting firm	**Cerenovus**
Contact	Ivenette Guzman

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