

K214025 PROWLER SELECT LP ES MicrocatheterApr 12, 2022
111 days to decisionK214025 · 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k214025/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026