

K210838 PROWLER SELECT PLUSAug 25, 2021
156 days to decisionK210838 · Product code: **KRA** · Neurology
Source: <https://www.510kdatabase.net/k210838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Continuous Flush (KRA)
Date received	Mar 22, 2021
Decision date	Aug 25, 2021
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	PROWLER EX

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Cerenovus
Contact	Samuel Shimp

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

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