

K220160 PediGuard ThreadedMar 31, 2022
71 days to decisionK220160 · Product code: **PDQ** · Neurology
Source: <https://www.510kdatabase.net/k220160/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurosurgical Nerve Locator (PDQ)
Date received	Jan 19, 2022
Decision date	Mar 31, 2022
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spineguard S.A.
Location	Washington, DC, US
Contact	Stephane Bette
510(k) history	6 submissions · 6 cleared · 2013-2022

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells LLP
Contact	John Smith

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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