

K202234 NervAlign Nerve CuffFeb 10, 2022
552 days to decisionK202234 · Product code: **JXI** · Neurology
Source: <https://www.510kdatabase.net/k202234/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cuff, Nerve (JXI)
Date received	Aug 7, 2020
Decision date	Feb 10, 2022
Days to decision	552 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Renerve, Ltd.
Location	North Melbourne, AU
Contact	David Rhodes
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Sloan Regulatory Consulting, LLC
Contact	Chris Sloan

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/k202234/> 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 27, 2026