

K190246 NeuroShieldMay 31, 2019
114 days to decisionK190246 · Product code: **JXI** · Neurology
Source: <https://www.510kdatabase.net/k190246/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cuff, Nerve (JXI)
Date received	Feb 6, 2019
Decision date	May 31, 2019
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Monarch Bioimplants GmbH
Location	Root, CH
Contact	Rivelino Montenegro
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190246/> 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 June 28, 2026