

**K221469 PATI (Protector Against Tongue Injury)**Feb 22, 2023  
278 days to decisionK221469 · Product code: **JXL** · Neurology  
Source: <https://www.510kdatabase.net/k221469/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Block, Bite (JXL)
Date received	May 20, 2022
Decision date	Feb 22, 2023
Days to decision	278 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Neurovice, LLC</b>
Location	Wake Forest, NC, US
Contact	Ashlyn Sanders
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Gilero, LLC</b>
Contact	John Hayes

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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221469/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026