

**K230201 Disposable Pre-calibrated Brain Biopsy Needle 2.0**Feb 22, 2023  
28 days to decisionK230201 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k230201/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jan 25, 2023
Decision date	Feb 22, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>PAJUNK GmbH Medizintechnologie</b>
Location	Geisingen, DE
Contact	Christian Quass
510(k) history	44 submissions · 44 cleared · 2006-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230201/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026