

**K201308 Axonpen, Axonmonitor, Axonbox, Tablet**Nov 27, 2020  
196 days to decisionK201308 · Product code: **GWG** · Neurology  
Source: <https://www.510kdatabase.net/k201308/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Neurological (GWG)
Date received	May 15, 2020
Decision date	Nov 27, 2020
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Clearmind Biomedical</b>
Location	Taipei, TW
Contact	Sheng-Chi Lin
510(k) history	3 submissions · 3 cleared · 2020-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201308/> 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 26, 2026