

**K242326 Wave Electrode (AE02-60)**Jan 2, 2025  
149 days to decisionK242326 · Product code: **GXY** · Neurology  
Source: <https://www.510kdatabase.net/k242326/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Aug 6, 2024
Decision date	Jan 2, 2025
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Wave Electrode (AE02-50)

**APPLICANT**

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Company	<b>Bionit Labs Srl</b>
Location	Soleto, IT
Contact	Aventaggiato Matteo
510(k) history	2 submissions · 2 cleared · 2025-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242326/> 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 14, 2026