

**K261522 BioWave BioWraps**Jun 3, 2026  
27 days to decisionK261522 · Product code: **GXY** · Neurology  
Source: <https://www.510kdatabase.net/k261522/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Cutaneous (GXY)
Date received	May 7, 2026
Decision date	Jun 3, 2026
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biowave Corporation</b>
Location	North Attleboro, MA, US
Contact	Bradford Siff
510(k) history	8 submissions · 8 cleared · 2005-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>MCRA, an IQVIA Business</b>
Contact	Emily Andre

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k261522/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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