FDA 510(k) Premarket Notification

K261522 BioWave BioWraps

CLEARED

Jun 3, 2026
27 days to decision

K261522 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k261522/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**MCRA, an IQVIA Business**
Contact	Emily Andre

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