

K203158 BioWave BioWrapsJul 8, 2021
259 days to decisionK203158 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k203158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Oct 22, 2020
Decision date	Jul 8, 2021
Days to decision	259 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	7 submissions · 7 cleared · 2005-2021

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Dave McGurl

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203158/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026