

K223605 ControlSeal Electrode (ELSB)Dec 30, 2022
28 days to decisionK223605 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k223605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Cutaneous (GXY)
Date received	Dec 2, 2022
Decision date	Dec 30, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Coapt
Location	Chicago, IL, US
Contact	Kevin Dwyer
510(k) history	2 submissions · 2 cleared · 2022-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223605/> 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