

K190416 Dome ElectrodeApr 4, 2019
42 days to decisionK190416 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k190416/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Electrode, Cutaneous (GXY)
Date received	Feb 21, 2019
Decision date	Apr 4, 2019
Days to decision	42 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Coapt, LLC
Location	Chicago, IL, US
Contact	Blair Lock
510(k) history	3 submissions · 3 cleared · 2017-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190416/> 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 June 28, 2026