

K192564 Disposable Gold Cup EEG ElectrodesJan 21, 2020
125 days to decisionK192564 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k192564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Sep 18, 2019
Decision date	Jan 21, 2020
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dymedix Diagnostics, Inc.
Location	Shoreview, MN, US
Contact	Todd Eiken
510(k) history	2 submissions · 2 cleared · 2020-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192564/> 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