

K182112 Sense System with IBT ElectrodesOct 5, 2018
60 days to decisionK182112 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k182112/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Aug 6, 2018
Decision date	Oct 5, 2018
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Infinite Biomedical Technologies, LLC
Location	Baltimore, MD, US
Contact	Rahul Kaliki
510(k) history	5 submissions · 5 cleared · 2009-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182112/> 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 27, 2026