

K180981 Stimulator Kit, Trial Kit, Spare Lead Kit, Wearable Assembly KitSep 19, 2018
159 days to decisionK180981 · Product code: **GZB** · Neurology
Source: <https://www.510kdatabase.net/k180981/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Spinal-cord, Implanted (pain Relief) (GZB)
Date received	Apr 13, 2018
Decision date	Sep 19, 2018
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stimwave Technologies Incorporated
Location	Miami Beach, FL, US
Contact	Elizabeth Greene
510(k) history	8 submissions · 8 cleared · 2014-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180981/>. 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