

K162161 Receiver Kit, Trial Kit, Spare Lead Kit, Sterile Revision Kit, Wearable Antenna Assembly Kit and Charger KitDec 16, 2016
136 days to decisionK162161 · Product code: **GZB** · Neurology
Source: <https://www.510kdatabase.net/k162161/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Spinal-cord, Implanted (pain Relief) (GZB)
Date received	Aug 2, 2016
Decision date	Dec 16, 2016
Days to decision	136 days
Third-party review	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/k162161/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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