

K182720 Freedom Spinal Cord Stimulator (SCS) SystemMar 29, 2019
182 days to decisionK182720 · Product code: **GZB** · Neurology
Source: <https://www.510kdatabase.net/k182720/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Spinal-cord, Implanted (pain Relief) (GZB)
Date received	Sep 28, 2018
Decision date	Mar 29, 2019
Days to decision	182 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

REGULATORY CONSULTANT

Consulting firm	Stimwave Technologies, Inc.
Contact	Elizabeth Greene

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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