K180981 Stimulator Kit, Trial Kit, Spare Lead Kit, Wearable Assembly Kit

CLEARED

Sep 19, 2018
159 days to decision

K180981 · 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