FDA 510(k) Premarket Notification

CLEARED

K162161 Receiver Kit, Trial Kit, Spare Lead Kit, Sterile Revision Kit, Wearable Antenna Assembly Kit and Charger Kit

Dec 16, 2016
136 days to decision

K162161 · 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