

K102115 ODFS PACEMar 30, 2011
245 days to decisionK102115 · Product code: **GZI** · Neurology
Source: <https://www.510kdatabase.net/k102115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Neuromuscular, External Functional (GZI)
Date received	Jul 28, 2010
Decision date	Mar 30, 2011
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Odstock Medical, Ltd.
Location	Salisbury, Wiltshire, GB
Contact	STEVEN CROOK
510(k) history	2 submissions · 2 cleared · 2011-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102115/> 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 May 31, 2026