

K143458 NeurosplintAug 13, 2015
252 days to decisionK143458 · Product code: **IQI** · Physical MedicineSource: <https://www.510kdatabase.net/k143458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Limb Brace (IQI)
Date received	Dec 4, 2014
Decision date	Aug 13, 2015
Days to decision	252 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Neurospectrum, LLC
Location	Rancho Mirage, CA, US
Contact	David Kernan
510(k) history	1 submissions · 1 cleared · 2015-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143458/> 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 June 4, 2026