FDA 510(k) Premarket Notification

K133638 GEKO

CLEARED

Aug 21, 2014
267 days to decision

K133638 · Product code: **IPF** · Physical Medicine
Source: https://www.510kdatabase.net/k133638/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Nov 27, 2013
Decision date	Aug 21, 2014
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Firstkind Limited**
Location	West Boylston, MA, US
Contact	SHEILA HEMEON-HEYER
510(k) history	11 submissions · 11 cleared · 2014-2022