FDA 510(k) Premarket Notification

K134001 FIREFLY

CLEARED

May 15, 2014
139 days to decision

K134001 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k134001/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Dec 27, 2013
Decision date	May 15, 2014
Days to decision	139 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