FDA 510(k) Premarket Notification

K160323 FlowKeepers

CLEARED

Apr 6, 2017
426 days to decision

K160323 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k160323/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Feb 5, 2016
Decision date	Apr 6, 2017
Days to decision	426 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dk Electronics, LLC**
Location	Sharon Hill, PA, US
Contact	AVERY HUFF
510(k) history	1 submissions · 1 cleared · 2017-2017