FDA 510(k) Premarket Notification

CLEARED

K180688 SLENDERTONE CoreFit Abs 8, Type 734

Oct 25, 2018
224 days to decision

K180688 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k180688/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Mar 15, 2018
Decision date	Oct 25, 2018
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Medical Research, Ltd.**
Location	Washington Dc, DC, US
Contact	Eoin Keating
510(k) history	32 submissions · 31 cleared · 1996-2021