FDA 510(k) Premarket Notification

K203513 SLENDERTONE Evolve Abs, Type 735

CLEARED

Feb 10, 2021
72 days to decision

K203513 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k203513/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Nov 30, 2020
Decision date	Feb 10, 2021
Days to decision	72 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