

K182581 PlayMakar Sport Muscle Stimulator, Model PRO-500Nov 21, 2018
63 days to decisionK182581 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k182581/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 19, 2018
Decision date	Nov 21, 2018
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Playmakar, Inc.
Location	Southlake, TX, US
Contact	Mike Williams
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Media Trade Corporation
Contact	Guenter Ginsberg

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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