

**K182794 BionicGym Powered Muscle Stimulator**Jul 18, 2019  
290 days to decisionK182794 · Product code: **NGX** · Physical Medicine  
Source: <https://www.510kdatabase.net/k182794/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Oct 1, 2018
Decision date	Jul 18, 2019
Days to decision	290 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medical Currents, Ltd.</b>
Location	Dublin 2, IE
Contact	Louis Crowe
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Donawa Lifescience Consulting Srl</b>
Contact	Roger Gray

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182794/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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