

**K201239 NuEra Tight Family, EMS Model**Dec 31, 2020  
238 days to decisionK201239 · Product code: **NGX** · Physical Medicine  
Source: <https://www.510kdatabase.net/k201239/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	May 7, 2020
Decision date	Dec 31, 2020
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bios S.R.L.</b>
Location	Silver Spring, MD, US
Contact	Maurizio Bianchi
510(k) history	14 submissions · 14 cleared · 2005-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201239/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026