

**K210002 STELLA BIO**Oct 1, 2021  
270 days to decisionK210002 · Product code: **IPF** · Physical MedicineSource: <https://www.510kdatabase.net/k210002/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Jan 4, 2021
Decision date	Oct 1, 2021
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Egzotech Sp. Z O. O.</b>
Location	Gliwice, PL
Contact	Michal Mikulski
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mdi Consultants, Inc.</b>
Contact	Vaibhav Arvind Rajal

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/k210002/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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