FDA 510(k) Premarket Notification

K210002 STELLA BIO

CLEARED

Oct 1, 2021
270 days to decision

K210002 · Product code: **IPF** · Physical Medicine
Source: https://www.510kdatabase.net/k210002/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Mdi Consultants, Inc.**
Contact	Vaibhav Arvind Rajal

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