

K203488 emFieldFeb 19, 2021
84 days to decisionK203488 · Product code: **IPF** · Physical Medicine
Source: <https://www.510kdatabase.net/k203488/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Nov 27, 2020
Decision date	Feb 19, 2021
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zimmer Medizinsysteme GmbH
Location	Neu-Ulm, DE
Contact	Ute Hauss
510(k) history	13 submissions · 13 cleared · 2016-2026

REGULATORY CONSULTANT

Consulting firm	Quality and Regulatory Services
Contact	Scott Blood

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

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