

K232786 Stimulation System (PA series, PR series, S series and Q series)May 16, 2024
248 days to decisionK232786 · Product code: **IPF** · Physical Medicine
Source: <https://www.510kdatabase.net/k232786/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Sep 11, 2023
Decision date	May 16, 2024
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Edan Instruments, Inc.
Location	Shenzhen, CN
Contact	Tracy Yue
Website	https://www.edan.com.cn
510(k) history	92 submissions · 92 cleared · 2004-2026

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