

K181688 R-C1 TENS and EMS StimulatorSep 7, 2018
73 days to decisionK181688 · Product code: **IPF** · Physical MedicineSource: <https://www.510kdatabase.net/k181688/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Jun 26, 2018
Decision date	Sep 7, 2018
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary
Other names	R-E1- EMS Stimulator; R-T1 TENS Stimulator

APPLICANT

Company	Shenzhen Roundwhale Technology Co. , Ltd.
Location	Shenzhen, CN
Contact	Kevin Zhang
510(k) history	7 submissions · 7 cleared · 2018-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181688/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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