

K182471 ScooterJul 10, 2019
303 days to decisionK182471 · Product code: **INI** · Physical Medicine
Source: <https://www.510kdatabase.net/k182471/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vehicle, Motorized 3-wheeled (INI)
Date received	Sep 10, 2018
Decision date	Jul 10, 2019
Days to decision	303 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tianjin Kepler Vehicle Industry Co. , Ltd.
Location	Tian Jin, CN
Contact	ChunXi Zhang
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

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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