

K201196 Scooter (Model: FDB01)Jun 25, 2021
417 days to decisionK201196 · Product code: **INI** · Physical Medicine
Source: <https://www.510kdatabase.net/k201196/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vehicle, Motorized 3-wheeled (INI)
Date received	May 4, 2020
Decision date	Jun 25, 2021
Days to decision	417 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nanjing Jin Bai HE Medical Apparatus Co., Ltd.
Location	Nanjing, CN
Contact	Dandan Yang
510(k) history	2 submissions · 2 cleared · 2017-2021

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Ivy 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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