

K203746 Venen-trainer (Model: FM150, SFM90)Nov 10, 2021
323 days to decisionK203746 · Product code: **JOW** · Cardiovascular
Source: <https://www.510kdatabase.net/k203746/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Dec 22, 2020
Decision date	Nov 10, 2021
Days to decision	323 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Pango Electronic Co., Ltd.
Location	Shanghai, CN
Contact	Guojun Zeng
510(k) history	9 submissions · 9 cleared · 2010-2021

REGULATORY CONSULTANT

Consulting firm	Guangzhou GLOMED Biological Technology Co., Ltd.
Contact	Cassie Lee

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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