

K230528 Extension SetDec 1, 2023
277 days to decisionK230528 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k230528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Feb 27, 2023
Decision date	Dec 1, 2023
Days to decision	277 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medcaptain Life Science Co., Ltd.
Location	Shenzhen, CN
Contact	Alan Tao
510(k) history	5 submissions · 5 cleared · 2021-2023

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