

K162601 Infusion Set for Single UseMay 31, 2017
254 days to decisionK162601 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k162601/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 19, 2016
Decision date	May 31, 2017
Days to decision	254 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shinva Ande Healthcare Apparatus Co., Ltd.
Location	Zibo, CN
Contact	Xiaolei Tian
510(k) history	6 submissions · 6 cleared · 2017-2022

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