

**K232475 Disposable infusion set with needle**May 10, 2024  
268 days to decisionK232475 · Product code: **FPA** · General HospitalSource: <https://www.510kdatabase.net/k232475/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Aug 16, 2023
Decision date	May 10, 2024
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Shandong Zhushi Pharmaceutical Group Co., Ltd.</b>
Location	Heze, CN
Contact	Junhui Zhu
510(k) history	8 submissions · 8 cleared · 2021-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Humiss, Inc.</b>
Contact	Bruce Cai

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232475/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026