

**K252543 AMSafe Administration Set (BA-70075, BA-70071-D, BA-70070, BA-70071-P, BA-70072, BA-70072-F, BA-70071-DF, BA-70071-DF-120, FE01, FE04)**May 4, 2026  
265 days to decisionK252543 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k252543/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Aug 12, 2025
Decision date	May 4, 2026
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Amsino International, Inc.</b>
Location	Ontario, CA, US
Contact	Jane Gao
510(k) history	28 submissions · 28 cleared · 2002-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252543/> 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 June 5, 2026