

**K043235 DRAGON HEART I.V. SET**Mar 8, 2005  
106 days to decisionK043235 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k043235/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Set, Administration, Intravascular (FPA)
Date received	Nov 22, 2004
Decision date	Mar 8, 2005
Days to decision	106 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Dragon Heart Medical Devices Co., Ltd.</b>
Location	Elmhurst, IL, US
Contact	JINA YU
510(k) history	2 submissions · 2 cleared · 2004-2005

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043235/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 2, 2026