

**K101368 D. HEART MEDICAL INTRAVASCULAR
ADMINISTRATION SET, SAFETY ACCES DEVICE AND
ACCESSORIES**Nov 18, 2010
185 days to decisionK101368 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k101368/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Set, Administration, Intravascular (FPA)
Date received	May 17, 2010
Decision date	Nov 18, 2010
Days to decision	185 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Dragon Heart Medical, Inc.
Location	Bensenville, IL, US
Contact	JINA YU
510(k) history	1 submissions · 1 cleared · 2010-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101368/> Data sourced from FDA 510(k) public records (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. - Generated June 20, 2026