

**K123605 SMARTFLOW CATHETER**Aug 16, 2013  
268 days to decisionK123605 · Product code: **HCA** · Neurology  
Source: <https://www.510kdatabase.net/k123605/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Ventricular (HCA)
Date received	Nov 21, 2012
Decision date	Aug 16, 2013
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Mri Interventions, Inc.</b>
Location	Irvine, CA, US
Contact	EDWARD F WADDELL
510(k) history	14 submissions · 14 cleared · 2011-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123605/> 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 June 18, 2026