

**K052509 M-BOLUS EMBOLIC MICROSPHERES**Dec 11, 2006  
454 days to decisionK052509 · Product code: **HCG** · Neurology  
Source: <https://www.510kdatabase.net/k052509/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Sep 13, 2005
Decision date	Dec 11, 2006
Days to decision	454 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Scion Cardio-Vascular, Inc.</b>
Location	Miami, FL, US
Contact	SUZANA OTANO-LATA
510(k) history	4 submissions · 4 cleared · 2004-2011

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k052509/> 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