

**K082580 SPECTRA GUIDEWIRE INTRODUCER NEEDLE**Dec 8, 2008  
94 days to decisionK082580 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k082580/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Sep 5, 2008
Decision date	Dec 8, 2008
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Spectra Medical Devices, Inc.</b>
Location	Williamsburg, VA, US
Contact	AGUSTIN TURRIZA
510(k) history	6 submissions · 6 cleared · 2008-2016

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082580/> 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 May 21, 2026