

**K103740 SODIUM CHLORIDE INJECTION, 0.9%, USP 5 ML, 10 ML AMPULE**Jul 29, 2011  
219 days to decisionK103740 · Product code: **NGT** · General Hospital  
Source: <https://www.510kdatabase.net/k103740/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saline, Vascular Access Flush (NGT)
Date received	Dec 22, 2010
Decision date	Jul 29, 2011
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spectra Medical Devices, Inc.</b>
Location	Williamsburg, VA, US
Contact	DAVID L ROSEN, B.S. PHARM., J.D.
510(k) history	6 submissions · 6 cleared · 2008-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103740/> 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