

**K011526 HYPERGLIDE OCCLUSION BALLOON SYSTEM,  
MODEL 104-4118, 104-4121, 104-4129, 104-4126, 104-4115,  
104-4123**Jun 14, 2001  
28 days to decisionK011526 · Product code: **MJN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k011526/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	May 17, 2001
Decision date	Jun 14, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Micro Therapeutics, Inc.</b>
Location	Aliso Viejo, CA, US
Contact	EBEN GORDON
510(k) history	51 submissions · 50 cleared · 1994-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011526/> 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 14, 2026