

**K091458 HYPERGLIDE OCCLUSION BALLOON SYSTEM,  
HYPERFORM OCCLUSION BALLOON SYSTEM, MODEL  
104-4112, 104-4113, 104-4127,104-4132,104**

Oct 15, 2009  
150 days to decision

K091458 · Product code: **MJN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k091458/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	May 18, 2009
Decision date	Oct 15, 2009
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ev3 Neurovascular</b>
Location	Lrvine, CA, US
Contact	TOM DAUGHTERS
510(k) history	3 submissions · 3 cleared · 2009-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k091458/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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