

K090728 HYPERGLIDE OCCLUSION BALLOON SYSTEMApr 16, 2009
28 days to decisionK090728 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k090728/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Mar 19, 2009
Decision date	Apr 16, 2009
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ev3, Inc.
Location	Plymouth, MN, US
Contact	JASON K LYON
510(k) history	35 submissions · 26 cleared · 2003-2014

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