

**K100063 HYPERFORM OCCLUSION BALLOON CATHETER,
HYPERGLIDE OCCLUSION BALLOON CATHETER,
HYPERGLIDE OCCLUSION BALLOON CATHETER MODEL**Feb 2, 2010
22 days to decisionK100063 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k100063/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Jan 11, 2010
Decision date	Feb 2, 2010
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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