

**K092495 HYPERGLIDE OCCLUSION BALLOON SYSTEM,
MODEL 104-4310, 104-4315**Sep 22, 2009
39 days to decisionK092495 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k092495/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Aug 14, 2009
Decision date	Sep 22, 2009
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ev3 Neurovascular
Location	Lrvine, CA, US
Contact	LAURIE E CARTWRIGHT
510(k) history	3 submissions · 3 cleared · 2009-2010

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