

**K940425 IMAGYN MEDICAL INFLATION DEVICE WITH NON-  
INVASIVE PRESSURE TUBING**Aug 1, 1994  
182 days to decisionK940425 · Product code: **MAV** · Cardiovascular  
Source: <https://www.510kdatabase.net/k940425/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Balloon Inflation (MAV)
Date received	Jan 31, 1994
Decision date	Aug 1, 1994
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Imagyn Medical, Inc.</b>
Location	San Clemente, CA, US
Contact	GUY R LOWERY
510(k) history	19 submissions · 19 cleared · 1991-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k940425/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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