

K082755 SEDAT FLAMINGODec 15, 2008
87 days to decisionK082755 · Product code: **MAV** · CardiovascularSource: <https://www.510kdatabase.net/k082755/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Balloon Inflation (MAV)
Date received	Sep 19, 2008
Decision date	Dec 15, 2008
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sedat
Location	San Diego, CA, US
Contact	CHARLES COUSIN
510(k) history	3 submissions · 3 cleared · 2006-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082755/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 24, 2026