

**K042449 DOLPHIN INFLATION DEVICE**Apr 18, 2005  
221 days to decisionK042449 · Product code: **MAV** · CardiovascularSource: <https://www.510kdatabase.net/k042449/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Balloon Inflation (MAV)
Date received	Sep 9, 2004
Decision date	Apr 18, 2005
Days to decision	221 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sedat S.A.</b>
Location	Charlestown, MA, US
Contact	LAETITIA BERNARD
510(k) history	2 submissions · 2 cleared · 2004-2005

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042449/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 2, 2026