

**K955869 SCIMED ENCORE 26 INFLATION DEVICE/ENCORE 30  
INFLATION DEVICE**Mar 22, 1996  
87 days to decisionK955869 · Product code: **MAV** · Cardiovascular  
Source: <https://www.510kdatabase.net/k955869/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Balloon Inflation (MAV)
Date received	Dec 26, 1995
Decision date	Mar 22, 1996
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Scimed Life Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	DIANE M LOWE
510(k) history	109 submissions · 108 cleared · 1977-1998

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k955869/> 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 29, 2026