

K133795 SUMMED INFLATION DEVICE KITDec 12, 2014
364 days to decisionK133795 · Product code: **MAV** · Cardiovascular
Source: <https://www.510kdatabase.net/k133795/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Balloon Inflation (MAV)
Date received	Dec 13, 2013
Decision date	Dec 12, 2014
Days to decision	364 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sunny Medical Device (Shenzhen) Co., Ltd.
Location	Irvine, CA, US
Contact	JAMES QI ZHANG
510(k) history	6 submissions · 6 cleared · 2012-2020

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