

K121637 AUTO-DISABLE STERILE SAFTY SYRING FOR SINGLE USEOct 25, 2012
143 days to decisionK121637 · Product code: **MEG** · General Hospital
Source: <https://www.510kdatabase.net/k121637/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Antistick (MEG)
Date received	Jun 4, 2012
Decision date	Oct 25, 2012
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sunwell Biotech Co., Ltd.
Location	Echo, OR, US
Contact	CHARLIE MACK
510(k) history	1 submissions · 1 cleared · 2012-2012

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