

K113186 STERILE INSULIN PEN NEEDLEApr 12, 2012
167 days to decisionK113186 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k113186/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Oct 28, 2011
Decision date	Apr 12, 2012
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shina Corp.
Location	Minneapolis, MN, US
Contact	JISEOP JEONG
510(k) history	3 submissions · 3 cleared · 2007-2012

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