

**K112332 FINE JECT INSULIN PEN NEEDLE**Jan 10, 2012  
151 days to decisionK112332 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k112332/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 12, 2011
Decision date	Jan 10, 2012
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Twobiens Co., Ltd.</b>
Location	Pittsburgh, PA, US
Contact	PETER CHUNG
510(k) history	1 submissions · 1 cleared · 2012-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112332/> 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 June 15, 2026