

K152166 JSM Insulin Pen NeedleJul 11, 2016
342 days to decisionK152166 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k152166/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 4, 2015
Decision date	Jul 11, 2016
Days to decision	342 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Jeesung Medical Co., Ltd.
Location	Daejeon, KR
Contact	CHOI YONG HYUN
510(k) history	3 submissions · 3 cleared · 2016-2022

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