

K181069 Disposable Insulin Pen NeedleAug 28, 2018
127 days to decisionK181069 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k181069/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Apr 23, 2018
Decision date	Aug 28, 2018
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zhejiang Kindly Medical Devices Co., Ltd.
Location	Wenzhou, CN
Contact	Yong Zhang
510(k) history	5 submissions · 5 cleared · 2018-2022

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