

K172483 Kopac Sterile NeedleJun 21, 2018
309 days to decisionK172483 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k172483/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 16, 2017
Decision date	Jun 21, 2018
Days to decision	309 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Poonglim Pharmatech, Inc.
Location	Gunsan, KR
Contact	Cho Hee Min
510(k) history	6 submissions · 6 cleared · 2018-2024

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