

K172095 AutokeeperJul 24, 2018
378 days to decisionK172095 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k172095/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jul 11, 2017
Decision date	Jul 24, 2018
Days to decision	378 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medexel Co.,Ltd
Location	Anseong-Si, KR
Contact	Cha Dong Ik
510(k) history	3 submissions · 3 cleared · 2016-2024

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