

K182268 EpiFaith Syringe (Luer Slip) , EpiFaith Syringe (NRFit)Apr 5, 2019
227 days to decisionK182268 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k182268/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Aug 21, 2018
Decision date	Apr 5, 2019
Days to decision	227 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Flat Medical Co., Ltd.
Location	Taipei, TW
Contact	Shao-Wei Tseng
510(k) history	3 submissions · 3 cleared · 2019-2022

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