

**K190002 Sterile Hypodermic Syringe for Single use,
with/without needle, Sterile Insulin Syringe for Single use, with
needle, Sterile Hypodermic needle for Single use**Sep 12, 2019
253 days to decisionK190002 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k190002/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jan 2, 2019
Decision date	Sep 12, 2019
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Kohope Medical Devices Co., Ltd.
Location	Shanghai, CN
Contact	Yibing Wang
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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