

**K210200 1 ml Sterile Hypodermic Syringe For Single Use.
With/Without Needle. Luer/Luer-Lock**May 14, 2021
109 days to decisionK210200 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k210200/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Jan 25, 2021
Decision date	May 14, 2021
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Set Medikal Sanayi VE Ticaret Anonim Sirketi
Location	Istanbul, TR
Contact	Mehice Ozturk
510(k) history	2 submissions · 2 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	Medcer Uluslararası Medikal Belgelendirme Anonim Sirketi
Contact	Mehmet Fatih Ormeci

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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