

**K201284 Sterile Hypodermic Syringe for Single Use,  
with/without needle, luer/luer-lock, Sterile Insulin Syringe for  
Single Use, with needle, Sterile Hypodermic needle for Single  
use**Dec 14, 2020  
215 days to decisionK201284 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k201284/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Syringe, Piston (FMF)
Date received	May 13, 2020
Decision date	Dec 14, 2020
Days to decision	215 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201284/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026