

**K250733 3DOSE 1ml Syringe**Jul 3, 2025  
114 days to decisionK250733 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k250733/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Mar 11, 2025
Decision date	Jul 3, 2025
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bimed Teknik Aletler Sanayi &amp; Ticaret A.S.</b>
Location	Istanbul, TR
Contact	Aysel Kilic
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250733/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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