

**K192770 S dispensing line**Dec 17, 2020  
444 days to decisionK192770 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k192770/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Sep 30, 2019
Decision date	Dec 17, 2020
Days to decision	444 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aea Srl</b>
Location	Angeli Di Rosora, IT
Contact	Michele Mengoni
510(k) history	3 submissions · 3 cleared · 2014-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192770/> 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 26, 2026