

**K202340 Droplet Pen Needle 30G & 33G**Oct 15, 2020  
59 days to decisionK202340 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k202340/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 17, 2020
Decision date	Oct 15, 2020
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Htl-Strefa S.A</b>
Location	Ozorkow, PL
Contact	Aleksandra Prazmowska-Wilanowska
510(k) history	7 submissions · 7 cleared · 2015-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202340/> 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