

**K252886 Pen Needle**Jan 6, 2026  
118 days to decisionK252886 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k252886/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 10, 2025
Decision date	Jan 6, 2026
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hh Global Technology, Inc.</b>
Location	Buford, GA, US
Contact	Grace Hammond
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Oconnell Regulatory Consultants, Inc.</b>
Contact	Maureen OConnell

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252886/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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