FDA 510(k) Premarket Notification

K252886 Pen Needle

CLEARED

Jan 6, 2026
118 days to decision

K252886 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k252886/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Oconnell Regulatory Consultants, Inc.**
Contact	Maureen OConnell

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