

K192082 Droplet Pen Needle 34GApr 21, 2020
263 days to decisionK192082 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k192082/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 2, 2019
Decision date	Apr 21, 2020
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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