

K171982 DROPLET PEN NEEDLEMar 21, 2018
264 days to decisionK171982 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k171982/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 30, 2017
Decision date	Mar 21, 2018
Days to decision	264 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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