

K211395 NIO-IJul 28, 2021
84 days to decisionK211395 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k211395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 5, 2021
Decision date	Jul 28, 2021
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Einstein Works, LLC
Location	Houston, TX, US
Contact	Roy Bachrach
510(k) history	3 submissions · 3 cleared · 2019-2021

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