

K231877 NavaClick Injection SystemNov 30, 2023
157 days to decisionK231877 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k231877/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jun 26, 2023
Decision date	Nov 30, 2023
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lineage Biomedical, Inc.
Location	Stuart, FL, US
Contact	Bradley Pliskow
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231877/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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