

K191359 Nipro SyringeOct 9, 2019
141 days to decisionK191359 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k191359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	May 21, 2019
Decision date	Oct 9, 2019
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nipro Medical Corporation
Location	Lexington, KY, US
Contact	Jessica Oswald-McLeod
510(k) history	34 submissions · 34 cleared · 2005-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191359/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026