

K160629 InPenJul 26, 2016
141 days to decisionK160629 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k160629/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Mar 7, 2016
Decision date	Jul 26, 2016
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Companion Medical, Inc.
Location	San Diego, CA, US
Contact	JASPER BENKE
510(k) history	5 submissions · 5 cleared · 2016-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160629/> 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 June 28, 2026