

K203738 QitexioMar 14, 2022
447 days to decisionK203738 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k203738/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Dec 22, 2020
Decision date	Mar 14, 2022
Days to decision	447 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medex
Location	Saint-Priest, FR
Contact	Sandra Thiolliere
510(k) history	2 submissions · 2 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Guerbet, LLC
Contact	Matthew Helmi

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203738/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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