

K242434 Insulin SyringesDec 24, 2024
130 days to decisionK242434 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k242434/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Aug 16, 2024
Decision date	Dec 24, 2024
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Chirana T. Injecta
Location	Star? Tur?, SK
Contact	Rastislav Broska
510(k) history	4 submissions · 4 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	Empirical Technologies
Contact	Nathan Wright

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/k242434/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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