

K201044 CHIRANA Insulin SyringesJan 18, 2022
637 days to decisionK201044 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k201044/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Apr 21, 2020
Decision date	Jan 18, 2022
Days to decision	637 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Empirical Testing Corp
Contact	Nathan Wright

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

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