FDA 510(k) Premarket Notification

K220614 MEDOJECT fine Pen Needles

CLEARED

Jun 15, 2022
104 days to decision

K220614 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k220614/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 3, 2022
Decision date	Jun 15, 2022
Days to decision	104 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