FDA 510(k) Premarket Notification

K192222 EZ-Inject Single use Needle

CLEARED

May 12, 2020
270 days to decision

K192222 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k192222/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 16, 2019
Decision date	May 12, 2020
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Poonglim Pharmatech, Inc.**
Location	Gunsan, KR
Contact	Cho Hee Min
510(k) history	6 submissions · 6 cleared · 2018-2024