CLEARED

K202319 Insulin Pen Needle (Ordinary Type), Insulin Pen Needle (Safety Type)

Nov 12, 2021
452 days to decision

K202319 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k202319/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 17, 2020
Decision date	Nov 12, 2021
Days to decision	452 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tianjin Huahong Technology Co., Ltd.**
Location	Tianjin, CN
Contact	Yan Li
510(k) history	11 submissions · 11 cleared · 2021-2026