FDA 510(k) Premarket Notification

K213183 Safety Insulin Pen Needles

CLEARED

Oct 14, 2022
380 days to decision

K213183 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k213183/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 29, 2021
Decision date	Oct 14, 2022
Days to decision	380 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zhejiang Kindly Medical Devices Co., Ltd.**
Location	Wenzhou, CN
Contact	Yong Zhang
510(k) history	5 submissions · 5 cleared · 2018-2022

REGULATORY CONSULTANT

Consulting firm	**Shanghai Mind-Link Business Consulting Co., Ltd.**
Contact	Alice Huang

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