FDA 510(k) Premarket Notification

K191853 Dual-Safety Pen Needle

CLEARED

Sep 5, 2019
57 days to decision

K191853 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k191853/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jul 10, 2019
Decision date	Sep 5, 2019
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Promisemed Hangzhou Meditech Co., Ltd.**
Location	Hangzhou, CN
Contact	Zearou Yang
510(k) history	35 submissions · 35 cleared · 2017-2026

REGULATORY CONSULTANT

Consulting firm	**Medtech Review, LLC**
Contact	John Beasley

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