FDA 510(k) Premarket Notification

K180259 Sterile Hypodermic Needle for Single Use

CLEARED

May 18, 2018
108 days to decision

K180259 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k180259/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 30, 2018
Decision date	May 18, 2018
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jiangsu Shenli Medical Production Co., Ltd.**
Location	Changzhou City, CN
Contact	Tina Cai
510(k) history	3 submissions · 3 cleared · 2017-2020

REGULATORY CONSULTANT

Consulting firm	**Irc**
Contact	Charles Mack

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