FDA 510(k) Premarket Notification

CLEARED

K193526 Syringe with safety needle, Safety needle

Jul 17, 2020
211 days to decision

K193526 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k193526/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Dec 19, 2019
Decision date	Jul 17, 2020
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jiangsu Caina Medical Co.,Ltd**
Location	Jiangyin, CN
Contact	Jianwei Pan
510(k) history	21 submissions · 21 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	**Mid-Link Consulting Co, Ltd.**
Contact	Diana Hong

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