FDA 510(k) Premarket Notification

K210217 Needleless Connector

CLEARED

May 17, 2021
110 days to decision

K210217 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k210217/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jan 27, 2021
Decision date	May 17, 2021
Days to decision	110 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