FDA 510(k) Premarket Notification

K222766 Disposable Extension Set

CLEARED

Apr 12, 2024
577 days to decision

K222766 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k222766/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 13, 2022
Decision date	Apr 12, 2024
Days to decision	577 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shandong Ande Healthcare Apparatus Co., Ltd.**
Location	Shandong, CN
Contact	Xiaolei Tian
510(k) history	1 submissions · 1 cleared · 2024-2024

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