FDA 510(k) Premarket Notification

CLEARED

K223645 I.V. Administration Set, I.V. Extension Set

May 18, 2023
163 days to decision

K223645 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k223645/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Dec 6, 2022
Decision date	May 18, 2023
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bq Plus Medical Co., Ltd.**
Location	Shanghai, CN
Contact	Jin Zhang
510(k) history	3 submissions · 3 cleared · 2021-2024

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