FDA 510(k) Premarket Notification

K233287 Vent Vial Adapter

CLEARED

Jul 26, 2024
301 days to decision

K233287 · Product code: **LHI** · General Hospital
Source: https://www.510kdatabase.net/k233287/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Sep 29, 2023
Decision date	Jul 26, 2024
Days to decision	301 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hangzhou Qiantang Longyue Biotechnology Co., Ltd.**
Location	Hangzhou, CN
Contact	Chunyu Wang
510(k) history	4 submissions · 4 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**Shanghai Lingfu Technology Co., Ltd.**
Contact	Esther Zhang

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