FDA 510(k) Premarket Notification

CLEARED

K241969 Hightop® Home Use Fentanyl/Norfentanyl Urine Rapid Test Panel

Aug 14, 2024
40 days to decision

K241969 · Product code: **NGL** · Toxicology
Source: https://www.510kdatabase.net/k241969/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Opiates, Over The Counter (NGL)
Date received	Jul 5, 2024
Decision date	Aug 14, 2024
Days to decision	40 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Hightop® Fentanyl/Norfentanyl Urine Rapid Test Panel

APPLICANT

Company	**Qingdao Hightop Biotech Co., Ltd.**
Location	Qingdao, CN
Contact	Ray Li
510(k) history	3 submissions · 3 cleared · 2019-2024

REGULATORY CONSULTANT

Consulting firm	**LSI International, Inc.**
Contact	Jenny Xia

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