FDA 510(k) Premarket Notification

K221038 Disposable Medical Masks

CLEARED

Sep 1, 2022
147 days to decision

K221038 · Product code: **FXX** · General Hospital
Source: https://www.510kdatabase.net/k221038/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Apr 7, 2022
Decision date	Sep 1, 2022
Days to decision	147 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hantech Medical Device Co., Ltd.**
Location	Ningbo, CN
Contact	Arnold Yang
510(k) history	5 submissions · 5 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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