FDA 510(k) Premarket Notification

K222335 Surgical Mask

CLEARED

Oct 11, 2022
69 days to decision

K222335 · Product code: **FXX** · General Hospital
Source: https://www.510kdatabase.net/k222335/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 3, 2022
Decision date	Oct 11, 2022
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Luoyang Sunmed Devices Co., Ltd.**
Location	Luoyang, CN
Contact	Tian Qian
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Joyantech Consulting Co., Ltd.**
Contact	Grace Liu

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