FDA 510(k) Premarket Notification

CLEARED

K210184 Wilson Tech Disposable Medical Face Mask

Sep 14, 2021
232 days to decision

K210184 · Product code: **FXX** · General Hospital
Source: https://www.510kdatabase.net/k210184/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jan 25, 2021
Decision date	Sep 14, 2021
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wilson Tech (International) Limited**
Location	Kowloon, HK
Contact	Ho Hang Terry Ting
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Shanghai Mind-Link Business Consulting Co., Ltd.**
Contact	Julie Chen

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k210184/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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