

K212046 Impertech Surgical Face MaskNov 18, 2021
141 days to decisionK212046 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k212046/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 30, 2021
Decision date	Nov 18, 2021
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Impertech Industries , Ltd.
Location	Barkan, IL
Contact	Mohamad Khweis
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Mdi Consultants, Inc.
Contact	Vaibhav Arvind Rajal

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

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