

K201182 iMask Disposable Surgical Face MaskFeb 19, 2021
294 days to decisionK201182 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k201182/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	May 1, 2020
Decision date	Feb 19, 2021
Days to decision	294 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Pac-Dent, Inc.
Location	Brea, CA, US
Contact	Jiahe Li
510(k) history	8 submissions · 8 cleared · 2020-2022

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