

K202069 BASE4 Disposable Medical MaskDec 1, 2020
127 days to decisionK202069 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202069/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Jul 27, 2020
Decision date	Dec 1, 2020
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Base4 Group, Inc.
Location	Addison, TX, US
Contact	Jon Filipski
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Benjamin L. England and Associates, LLC
Contact	Thomas C. Knott

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202069/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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