

K201127 DEFEND Ear-loop Face MasksApr 14, 2021
351 days to decisionK201127 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k201127/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Apr 28, 2020
Decision date	Apr 14, 2021
Days to decision	351 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Young Dental Manufacturing Co. 1, LLC
Location	Mchenry, IL, US
Contact	Jose Espino
510(k) history	16 submissions · 16 cleared · 1977-2025

REGULATORY CONSULTANT

Consulting firm	Young Dental Manufacturing Co.
Contact	Jose Espino

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

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