

**K253398 Disposable Surgical Mask (Non-Sterile)  
(EFX3PLBLKMSK300)**Feb 19, 2026  
142 days to decisionK253398 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k253398/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mask, Surgical (FXX)
Date received	Sep 30, 2025
Decision date	Feb 19, 2026
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Efofex, Inc.</b>
Location	Rogers, AR, US
Contact	Siddhant Doshi
510(k) history	2 submissions · 2 cleared · 2023-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mdi Consultants, Inc.</b>
Contact	Vaibhav Rajal

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253398/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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