

**K201137 Asept Surgical Face Mask**Aug 19, 2020  
113 days to decisionK201137 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k201137/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Apr 28, 2020
Decision date	Aug 19, 2020
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pfm Medical, Inc.</b>
Location	Oceanside, CA, US
Contact	Jessica Jho
510(k) history	20 submissions · 17 cleared · 2004-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201137/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026