

**K221209 PRECISION ECO Compostable / Plant Based  
Procedural Mask with Earloops**

Mar 8, 2023  
316 days to decision

K221209 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k221209/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Apr 26, 2022
Decision date	Mar 8, 2023
Days to decision	316 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Padm Medical, Inc.</b>
Location	Winnipeg, CA
Contact	Xiomara Perdomo
510(k) history	1 submissions · 1 cleared · 2023-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k221209/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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