

**K211105 Ear-Friendly Mask**May 17, 2021  
34 days to decisionK211105 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k211105/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Apr 13, 2021
Decision date	May 17, 2021
Days to decision	34 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ray Co., Ltd.</b>
Location	Beverly Hills, CA, US
Contact	Changhwan Lee
510(k) history	24 submissions · 24 cleared · 2013-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Accelerated Device Approval Services</b>
Contact	Rafael Aguila

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211105/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026