

**K201852 Surgical Mask-Model Number: Ear Loop, Flat-Pleated**Mar 2, 2021  
239 days to decisionK201852 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k201852/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Jul 6, 2020
Decision date	Mar 2, 2021
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Huizhou Foryou Medical Devices Co., Ltd.</b>
Location	Pennington, NJ, US
Contact	Guosheng Tan
510(k) history	22 submissions · 22 cleared · 2012-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201852/> 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 13, 2026