

**K201380 Livocare Surgical Mask**Oct 7, 2020  
134 days to decisionK201380 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k201380/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	May 26, 2020
Decision date	Oct 7, 2020
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Andon Health Co, Ltd.</b>
Location	Tiajin, CN
Contact	Liu Yi
510(k) history	92 submissions · 92 cleared · 2008-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201380/> 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