

**K202655 Disposable Medical Mask**Apr 5, 2021  
203 days to decisionK202655 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k202655/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Mask, Surgical (FXX)               |
| Date received         | Sep 14, 2020                       |
| Decision date         | Apr 5, 2021                        |
| Days to decision      | 203 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |  |
|----------------|--|
| Company        | <b>Dongguan Runlin Medical Supplies Technology Co., Ltd.</b> |
| Location       | Dongguan, CN   |
| Contact        | Weiming Chen   |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021                        |

**REGULATORY CONSULTANT**

---

|                 |   |
|-----------------|---|
| Consulting firm | <b>Share Info (Guangzhou) Medical Consultant , Ltd.</b> |
| Contact         | Cassie Lee  |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202655/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026