

**K202137 Disposable medical mask**Mar 4, 2021  
216 days to decisionK202137 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k202137/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Mask, Surgical (FXX)               |
| Date received         | Jul 31, 2020                       |
| Decision date         | Mar 4, 2021                        |
| Days to decision      | 216 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>U-Play Products Corporation</b>    |
| Location       | Wuhu, CN                              |
| Contact        | Jin Jing                              |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

**REGULATORY CONSULTANT**

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|-----------------|--|
| Consulting firm | <b>Shanghai Sungo Management Consulting Company Limited.</b> |
| Contact         | Ivy Wang   |

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202137/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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