

**K211497 Surgical Mask**Jul 28, 2021  
75 days to decisionK211497 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k211497/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Mask, Surgical (FXX)               |
| Date received         | May 14, 2021                       |
| Decision date         | Jul 28, 2021                       |
| Days to decision      | 75 days                            |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Honeywell Safety Products</b>      |
| Location       | Smithfield, RI, US                    |
| Contact        | Ivy Pettis                            |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211497/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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