

**K191355 3M™ High Fluid-Resistant Surgical Mask and 3M™ High Fluid-Resistant Procedure Mask**

Sep 11, 2019  
113 days to decision

K191355 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k191355/>

**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Mask, Surgical (FXX)               |
| Date received         | May 21, 2019                       |
| Decision date         | Sep 11, 2019                       |
| Days to decision      | 113 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>3M Healthcare</b>                    |
| Location       | St. Paul, MN, US                        |
| Contact        | Angie Draper                            |
| 510(k) history | 21 submissions · 20 cleared · 1991-2020 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k191355/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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