

**K233022 Halyard Fluidshield 3 N95 Particulate Filter Respirator and Surgical Mask with So Soft Lining, Orange, Regular and Small, Halyard Fluidshield 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and So Soft Lining, Orange, Regular and Small, Halyard Fluidshield 2 N95 Particulate Filter Respirator and Surgical Mask with So Soft Lining, White, Regular and Small**

Jan 12, 2024  
112 days to decision

K233022 · Product code: **MSH** · General Hospital  
Source: <https://www.510kdatabase.net/k233022/>

**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Respirator, Surgical (MSH)         |
| Date received         | Sep 22, 2023                       |
| Decision date         | Jan 12, 2024                       |
| Days to decision      | 112 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|--|
| Company        | <b>Owens &amp; Minor (O&amp;M) Halyard, Inc.</b> |
| Location       | Mechanicsville, VA, US                           |
| Contact        | Anureet Singh                                    |
| 510(k) history | 12 submissions · 12 cleared · 2019-2025          |

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