

K210772 3-Layer Medical Face Masks (XMM3L3C), 3-Layer Medical Face Masks with ties (XMM3HT)Sep 22, 2021
191 days to decisionK210772 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k210772/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mask, Surgical (FXX) |
| Date received | Mar 15, 2021 |
| Decision date | Sep 22, 2021 |
| Days to decision | 191 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Vr Vertical, LLC DbA Xrgo |
| Location | Louisville, KY, US |
| Contact | Matthew DiPalma |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

REGULATORY CONSULTANT

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|-----------------|-----------------------------|
| Consulting firm | Vr Vertical DbA Xrgo |
| Contact | Nathaniel Victor |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210772/> 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 26, 2026