

K211772 PMW01 Procedure Mask Level 1Dec 6, 2021
181 days to decisionK211772 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k211772/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Mask, Surgical (FXX) |
| Date received | Jun 8, 2021 |
| Decision date | Dec 6, 2021 |
| Days to decision | 181 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Defender Safety, Inc. |
| Location | Plainview, NY, US |
| Contact | Nahal Islam |
| 510(k) history | 2 submissions · 2 cleared · 2021-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211772/> 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