

K201844 Surgical Face Mask, Surgical MaskJul 14, 2021
373 days to decisionK201844 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k201844/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Mask, Surgical (FXX) |
| Date received | Jul 6, 2020 |
| Decision date | Jul 14, 2021 |
| Days to decision | 373 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Lear Corporation |
| Location | Pine Grove, PA, US |
| Contact | Ryan Facer |
| Website | http://www.lear.com/ |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201844/> 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 27, 2026