

K152561 Communicator Surgical Facemask with Clear WindowJun 3, 2016
268 days to decisionK152561 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k152561/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Mask, Surgical (FXX) |
| Date received | Sep 9, 2015 |
| Decision date | Jun 3, 2016 |
| Days to decision | 268 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Prestige Ameritech , Ltd. |
| Location | North Richland Hills, TX, US |
| Contact | Rex Reese |
| 510(k) history | 1 submissions · 1 cleared · 2016-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152561/> 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 June 2, 2026