

K082258 CROSSTEX ISOLITE AND ISOFLUID EARLOOP FACE MASKS AND ISOFLUID FOGFREE FACE MASKS WITH AND WITHOUT SPLASH VISOR

Oct 16, 2008
69 days to decision

K082258 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k082258/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mask, Surgical (FXX) |
| Date received | Aug 8, 2008 |
| Decision date | Oct 16, 2008 |
| Days to decision | 69 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Crosstex International |
| Location | Minneapolis, MN, US |
| Contact | RICHARD M ORMSBEE |
| 510(k) history | 4 submissions · 4 cleared · 2008-2014 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k082258/> 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 5, 2026