

K920108 BARRIER EXTRA PROTECTION PLUS FACE MASKFeb 10, 1994
762 days to decisionK920108 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k920108/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mask, Surgical (FXX) |
| Date received | Jan 10, 1992 |
| Decision date | Feb 10, 1994 |
| Days to decision | 762 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|--|
| Company | Johnson & Johnson Medical, Inc. |
| Location | Arlington, TX, US |
| Contact | WENDT |
| 510(k) history | 53 submissions · 50 cleared · 1990-2000 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k920108/> 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 28, 2026