

K884076 SUREBREATH DOMEOct 7, 1988
10 days to decisionK884076 · Product code: **GAD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k884076/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Retractor (GAD) |
| Date received | Sep 27, 1988 |
| Decision date | Oct 7, 1988 |
| Days to decision | 10 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Ipax, Inc. |
| Location | CO, US |
| Contact | PENNELL |
| 510(k) history | 18 submissions · 18 cleared · 1984-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k884076/>; 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