

**K960401 ULTIMATE SEAL**Jun 20, 1996  
143 days to decisionK960401 · Product code: **KGB** · Anesthesiology  
Source: <https://www.510kdatabase.net/k960401/>**SUBMISSION DETAILS**

---

|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | Mask, Oxygen, Non-rebreathing (KGB) |
| Date received         | Jan 29, 1996                        |
| Decision date         | Jun 20, 1996                        |
| Days to decision      | 143 days                            |
| Third-party review    | No                                  |
| Summary / Statement   | Statement                           |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Hans Rudolph, Inc.</b>               |
| Location       | Mchenry, IL, US                         |
| Contact        | KEVIN RUDOLPH                           |
| 510(k) history | 11 submissions · 11 cleared · 1979-2008 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k960401/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 24, 2026