

**K964136 HYSTERO CO2-PNEU 2221**Jan 10, 1997  
87 days to decisionK964136 · Product code: **HIG** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k964136/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Insufflator, Hysteroscopic (HIG)   |
| Date received         | Oct 15, 1996                       |
| Decision date         | Jan 10, 1997                       |
| Days to decision      | 87 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Richard Wolf Medical Instruments Corp.</b> |
| Location       | Mchenry, IL, US                               |
| Contact        | ROBERT L CASARSA                              |
| 510(k) history | 142 submissions · 142 cleared · 1977-2016     |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964136/> 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 14, 2026