

**K001270 GYRUS ENDOUROLOGY SYSTEM: AXIPOLAR
RESECTOSCOPE LOOP ELECTRODE**Apr 28, 2000
8 days to decisionK001270 · Product code: **FJL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k001270/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Resectoscope (FJL) |
| Date received | Apr 20, 2000 |
| Decision date | Apr 28, 2000 |
| Days to decision | 8 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Gyrus Medical , Ltd. |
| Location | England, GB |
| Contact | DAVID KAY |
| 510(k) history | 8 submissions · 8 cleared · 1990-2004 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001270/>. 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 29, 2026