

K941781 RIGISCAN PLUS RIGIDITY ASSESSMENT SYSTEMAug 25, 1994
136 days to decisionK941781 · Product code: **LIL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k941781/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Penile Tumescence (LIL) |
| Date received | Apr 11, 1994 |
| Decision date | Aug 25, 1994 |
| Days to decision | 136 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Dacomed Corp. |
| Location | Mchenry, IL, US |
| Contact | MARY M WILEN |
| 510(k) history | 20 submissions · 20 cleared · 1981-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k941781/> 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 July 1, 2026