

K771650 AKRO-SIL FOLEY KIT 30CCSep 20, 1977
22 days to decisionK771650 · Product code: **FCM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k771650/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM) |
| Date received | Aug 29, 1977 |
| Decision date | Sep 20, 1977 |
| Days to decision | 22 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Latex Ind., Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 14 submissions · 14 cleared · 1977-1981 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k771650/> 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 4, 2026