

K000578 SERIM LEUKOCYTE ESTERASE TEST STRIPSMay 5, 2000
73 days to decisionK000578 · Product code: **LJX** · Hematology
Source: <https://www.510kdatabase.net/k000578/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Test, Urine Leukocyte (LJX) |
| Date received | Feb 22, 2000 |
| Decision date | May 5, 2000 |
| Days to decision | 73 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------------------------|
| Company | Serim Research Corp. |
| Location | Elkhart, IN, US |
| Contact | ROBERT J CARRICO |
| Website | https://www.serim.com |
| 510(k) history | 27 submissions · 27 cleared · 1990-2012 |

Serim Research Corp. develops and manufactures diagnostic test strips based on proprietary dry reagent technology. The company operates a fully integrated research and development and manufacturing facility in Elkhart, Indiana. Since 1988, Serim has specialized in colorimetric chemistries, reagent impregnation, and test strip fabrication for medical and industrial applications. The company received FDA 510(k) clearances from total submissions, with all submissions resulting in clearance. Serim's cleared devices focus on gastroenterology and urology applications, including...
