

**K911628 SERIM FORMALDEHYDE REAGENT STRIPS (1.0%
-2.0%)**Jun 27, 1991
77 days to decisionK911628 · Product code: **LIF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k911628/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dialyzer Reprocessing System (LIF) |
| Date received | Apr 11, 1991 |
| Decision date | Jun 27, 1991 |
| Days to decision | 77 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Serim Research Corp. |
| Location | Elkhart, IN, US |
| Contact | MICHAEL MCKENNA |
| 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...

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