

**K911629 SERIM FORMALDEHYDE REAGENT STRIPS (2.5%  
-4.0%)**Jun 27, 1991  
77 days to decisionK911629 · Product code: **LIF** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k911629/>**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**

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Company	<b>Serim Research Corp.</b>
Location	Elkhart, IN, US
Contact	MICHAEL MCKENNA
Website	<a href="https://www.serim.com">https://www.serim.com</a>
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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