

K902227 SERIM GLUTARALDEHYDE/NEPHREX POTENCY TEST KITApr 2, 1991
320 days to decisionK902227 · Product code: **LIF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k902227/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer Reprocessing System (LIF)
Date received	May 17, 1990
Decision date	Apr 2, 1991
Days to decision	320 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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