

K914123 SERIM RESIDUAL FORMALDEHYDE REAGENT STRIPSApr 9, 1992
209 days to decisionK914123 · Product code: **LIF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k914123/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer Reprocessing System (LIF)
Date received	Sep 13, 1991
Decision date	Apr 9, 1992
Days to decision	209 days
Third-party review	No
Summary / Statement	Statement

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...