

K953632 SERIM PYLORITEK TEST KITDec 18, 1995
151 days to decisionK953632 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k953632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Jul 20, 1995
Decision date	Dec 18, 1995
Days to decision	151 days
Third-party review	No
Summary / Statement	Statement

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...
