

K945491 SERIM(TM) BICARB PH REAGENT STRIPSFeb 1, 1995
85 days to decisionK945491 · Product code: **MNV** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k945491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Strip, Dialysate Ph Indicator (MNV)
Date received	Nov 8, 1994
Decision date	Feb 1, 1995
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Serim Research Corp.
Location	Elkhart, IN, US
Contact	ROBERT C BOGUSLASKI
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...
