

**K936034 SERIM PYLORITEK REAGENT STRIPS**Apr 21, 1994  
127 days to decisionK936034 · Product code: **JTO** · Microbiology  
Source: <https://www.510kdatabase.net/k936034/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Discs, Strips And Reagents, Microorganism Differentiation (JTO)
Date received	Dec 15, 1993
Decision date	Apr 21, 1994
Days to decision	127 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Serim Research Corp.</b>
Location	Elkhart, IN, US
Contact	J. 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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