

**K932047 WAVICIDE MONITOR STRIPS**Jun 2, 1994  
401 days to decisionK932047 · Product code: **MED** · General Hospital  
Source: <https://www.510kdatabase.net/k932047/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilant, Medical Devices (MED)
Date received	Apr 27, 1993
Decision date	Jun 2, 1994
Days to decision	401 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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