

**K012115 SERIM BLOOD LEAK TEST STRIP-2**Nov 30, 2001  
147 days to decisionK012115 · Product code: **FJD** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k012115/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector, Leak, Blood (FJD)
Date received	Jul 6, 2001
Decision date	Nov 30, 2001
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---