

K990206 SERIM BLOOD LEAK TEST STRIPApr 21, 1999
90 days to decisionK990206 · Product code: **FJD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k990206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector, Leak, Blood (FJD)
Date received	Jan 21, 1999
Decision date	Apr 21, 1999
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

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...
