

K080712 SERIM HISENSE ULTRA 0.1, PART NUMBER 5167May 6, 2008
54 days to decisionK080712 · Product code: **MSY** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k080712/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Strip, Test, Reagent, Residuals For Dialysate, Disinfectant (MSY)
Date received	Mar 13, 2008
Decision date	May 6, 2008
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Serim Research Corp.
Location	Elkhart, IN, US
Contact	PATRICIA RUPCHOCK
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...
