

K083295 SERIM DISINTEK GTA 2.1%, MODEL: 5164Mar 16, 2009
126 days to decisionK083295 · Product code: **JOJ** · General Hospital
Source: <https://www.510kdatabase.net/k083295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Physical/chemical Sterilization Process (JOJ)
Date received	Nov 10, 2008
Decision date	Mar 16, 2009
Days to decision	126 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...
