

K163511 NovaGuard SA Pro Safety SystemFeb 2, 2017
49 days to decisionK163511 · Product code: **MEG** · General Hospital
Source: <https://www.510kdatabase.net/k163511/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Antistick (MEG)
Date received	Dec 15, 2016
Decision date	Feb 2, 2017
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	West Pharmaceutical Services, Inc.
Location	Lionville, PA, US
Contact	Ana Ladino
Website	http://www.westpharma.com/
510(k) history	6 submissions · 6 cleared · 2004-2024

West Pharmaceutical Services, Inc. is a leading provider of innovative injectable solutions and packaging components for the pharmaceutical and medical device industries. The company specializes in drug containment and delivery systems, with a manufacturing facility in Lionville, US. West serves established and emerging drug developers worldwide, shipping approximately 43 billion components and devices annually across 50 global sites. West has received FDA 510(k) clearances from total submissions, with all submissions focused on General Hospital devices. The company's reg...

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