

K082908 NOVAGUARD, MODEL 3611001Apr 24, 2009
206 days to decisionK082908 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k082908/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 30, 2008
Decision date	Apr 24, 2009
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	West Pharmaceutical Services, Inc.
Location	Lionville, PA, US
Contact	ARI Y SOBEL
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...
