

**K122837 AUTOJECT 2 FOR GLASSY SYRINGE**Oct 15, 2012  
28 days to decisionK122837 · Product code: **KZH** · General Hospital  
Source: <https://www.510kdatabase.net/k122837/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Syringe Needle (KZH)
Date received	Sep 17, 2012
Decision date	Oct 15, 2012
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Owen Mumford, Ltd.</b>
Location	Marietta, GA, US
Contact	DARREN MANSELL
Website	<a href="http://www.owenmumford.com/us/">http://www.owenmumford.com/us/</a>
510(k) history	13 submissions · 13 cleared · 2000-2023

Owen Mumford, Ltd. is a global medical device manufacturer with over 70 years of experience designing and manufacturing innovative healthcare solutions. The company specializes in drug delivery systems, blood collection devices, and safety lancets for both clinical and home use. Owen Mumford operates with a manufacturing facility in Marietta, US, and serves healthcare professionals and patients worldwide. The company has received FDA 510(k) clearances from total submissions, spanning from 2000 to 2023. Owen Mumford's cleared devices focus primarily on General Hospital app...

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