

**K062318 BIOTOP HOOKSAFE U-100 INSULIN SYRINGE,  
MODELS 0.5CC/ML AND 1CC/ML**Jan 3, 2007  
147 days to decisionK062318 · Product code: **MEG** · General Hospital  
Source: <https://www.510kdatabase.net/k062318/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Antistick (MEG)
Date received	Aug 9, 2006
Decision date	Jan 3, 2007
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biotop Technology Co., Ltd.</b>
Location	Hsin Chu City, TW
Contact	LYDIA LEE
510(k) history	4 submissions · 4 cleared · 2004-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062318/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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