

**K160532 Greiner Holdex**Nov 3, 2016  
251 days to decisionK160532 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k160532/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 26, 2016
Decision date	Nov 3, 2016
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Greiner Bio-One Na, Inc.</b>
Location	Monroe, NC, US
Contact	MANFRED ABEL
510(k) history	5 submissions · 5 cleared · 2016-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160532/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026