

**K171144 Medifine Pen Needle 3 Bevel, Medifine Pen Needle  
Quinta 5 Bevel**Sep 12, 2017  
146 days to decisionK171144 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k171144/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Apr 19, 2017
Decision date	Sep 12, 2017
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medbio, LLC</b>
Location	Cooper City, FL, US
Contact	Jatin Rajani
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171144/>; 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 May 31, 2026