

**K163578 EasyTouch Safety Pen Needle**Aug 3, 2018  
591 days to decisionK163578 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k163578/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Dec 20, 2016
Decision date	Aug 3, 2018
Days to decision	591 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mhc Medical Products, LLC</b>
Location	Naples, FL, US
Contact	John Edmiston
510(k) history	2 submissions · 2 cleared · 2011-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163578/> 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 30, 2026