

**K050464 ULTRACARE DISPOSABLE PEN NEEDLES, MODELS  
31 GAUGE X3/16, 29 GAUGE X 1/2**May 11, 2005  
77 days to decisionK050464 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k050464/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 23, 2005
Decision date	May 11, 2005
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ultimed, Inc.</b>
Location	St. Paul, MN, US
Contact	CAROLE STAMP
510(k) history	8 submissions · 8 cleared · 2000-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050464/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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