

**K213407 UltiCare Disposable Pen Needles**Dec 16, 2021  
58 days to decisionK213407 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k213407/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Oct 19, 2021
Decision date	Dec 16, 2021
Days to decision	58 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ultimed Incorporated</b>
Location	Minneapolis, MN, US
Contact	Paul Lewis
510(k) history	2 submissions · 2 cleared · 2015-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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