

K100812 ULTICARE DISPOSABLE PEN NEEDLESJun 3, 2010
72 days to decisionK100812 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k100812/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 23, 2010
Decision date	Jun 3, 2010
Days to decision	72 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Ultimed, Inc.
Location	St. Paul, MN, US
Contact	MARY BETH HENDERSON
510(k) history	8 submissions · 8 cleared · 2000-2010

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