

K131125 CLICKFINE PEN NEEDLEJul 5, 2013
74 days to decisionK131125 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k131125/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Apr 22, 2013
Decision date	Jul 5, 2013
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ypsomed AG
Location	Burgdorf, CH
Contact	BENJAMIN REINMANN
510(k) history	12 submissions · 12 cleared · 2010-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131125/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026