

K010887 INSULIN PEN NEEDLE ADAPTERJun 8, 2001
74 days to decisionK010887 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k010887/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 26, 2001
Decision date	Jun 8, 2001
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ohana Needle Co.
Location	Andover, MA, US
Contact	SPENCER H OWADES
510(k) history	1 submissions · 1 cleared · 2001-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010887/> 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 July 4, 2026