

K011757 EXEL COMFORTPOINT INSULIN PEN NEEDLEJan 23, 2002
231 days to decisionK011757 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k011757/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 6, 2001
Decision date	Jan 23, 2002
Days to decision	231 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Exelint Intl. Co.
Location	Culver City, CA, US
Contact	ARMAND HAMID
510(k) history	12 submissions · 12 cleared · 2000-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011757/> 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 June 21, 2026