

K813649 PBC NEEDLEJan 28, 1982
28 days to decisionK813649 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k813649/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Dec 31, 1981
Decision date	Jan 28, 1982
Days to decision	28 days
Third-party review	No

APPLICANT

Company	Philadelphia Biologics Center
Location	Mchenry, IL, US
510(k) history	11 submissions · 11 cleared · 1982-1984

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k813649/> 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 9, 2026