

K813545 HYPOSERMIC NEEDLESJan 12, 1982
22 days to decisionK813545 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k813545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Dec 21, 1981
Decision date	Jan 12, 1982
Days to decision	22 days
Third-party review	No

APPLICANT

Company	Optical Micro Systems, Inc.
Location	Mchenry, IL, US
510(k) history	21 submissions · 21 cleared · 1981-1995

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k813545/> 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 29, 2026