

**K802011 INFUSION ALARM SYSTEM I.A.S. CAT.#1118**Oct 31, 1980  
72 days to decisionK802011 · Product code: **FLN** · General HospitalSource: <https://www.510kdatabase.net/k802011/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Electric For Gravity Flow Infusion Systems (FLN)
Date received	Aug 20, 1980
Decision date	Oct 31, 1980
Days to decision	72 days
Third-party review	No

**APPLICANT**

---

Company	<b>Pollak (Intl.), Ltd.</b>
Location	Mchenry, IL, US
510(k) history	31 submissions · 31 cleared · 1980-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k802011/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026