

K952799 ABBOTT XL3M INFUSION PUMPJan 18, 1996
213 days to decisionK952799 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k952799/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pump, Infusion (FRN) |
| Date received | Jun 19, 1995 |
| Decision date | Jan 18, 1996 |
| Days to decision | 213 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Abbott Laboratories |
| Location | Abbott Park, IL, US |
| Contact | DAVID T GUZEK |
| Website | http://www.abbott.com |
| 510(k) history | 883 submissions · 868 cleared · 1976-2026 |

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...
