

**K042121 SPECTRUM AND SPECTRUM WITH MASTER DRUG
LIBRARY**Aug 26, 2004
20 days to decisionK042121 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k042121/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pump, Infusion (FRN) |
| Date received | Aug 6, 2004 |
| Decision date | Aug 26, 2004 |
| Days to decision | 20 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Sigma Intl. |
| Location | Medina, NY, US |
| Contact | CHARLES L MARTINA |
| 510(k) history | 3 submissions · 3 cleared · 1994-2004 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042121/> 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 2, 2026